American National Standard

ANSI/AAMI ST35:2003

Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings

AAMI Association for the Advancement of Medical Instrumentation

Documents Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003: Safe handling and biological decontamination of reusable medical devices in health care facilities and i

Single user license only. Copying, networking, and distribution prohibited.

The 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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 decisionmaking.

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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user licence only, copying, networking and distribution prohibited.

American National Standard

ANSI/AAMI ST35:2003
(Revision of ANSI/AAMI ST35:1996)

Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings

Developed by
Association for the Advancement of Medical Instrumentation

Approved 17 March 2003 by
American National Standards Institute, Inc.

Abstract: This recommended practice covers the safe handling and biological decontamination of reusable medical devices, including design criteria for decontamination areas in health care facilities; staff qualifications, education, and other personnel considerations; immediate handling of contaminated items; transport of contaminated items; and decontamination processes. This recommended practice also includes definitions of terms and reference documents, as well as informative annexes providing supplementary information on the principles of infection transmission; the selection and use of chemical disinfectants; thermal disinfection; the safe handling and decontamination of medical devices returned to manufacturers for servicing, repair, or failure investigation; and the OSHA bloodborne pathogen regulation.

Keywords: cleaning, disinfection, hazardous materials, infection control, microbicidal processes, sterilization

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

AAMI Recommended Practice

This Association for the Advancement of Medical Instrumentation (AAMI) recommended practice implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI recommended practice does not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice. AAMI recommended practices are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI recommended practice may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this recommended practice no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards and recommended practices by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

© 2003 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1–57020–193–5

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

Contents

Page

Glossary of equivalent standards vi

Committee representation viii

Foreword x

Introduction: Need for the recommended practice xi

1 Scope 1

1.1 General 1
1.2 Inclusions 1
1.3 Exclusions 1

2 Definitions, symbols, and abbreviations 2

3 Design considerations 4

3.1 General rationale 4
3.2 Centralization of decontamination 4
3.3 Design criteria 4
3.4 Work area design 6
3.4.1 Physical layout 6
3.4.2 Functional work flow patterns 7
3.4.3 Ceilings, floors, walls, and work stations 7
3.4.4 Ventilation 7
3.4.5 Temperature and humidity 8
3.4.6 Lighting 8
3.5 Traffic control 8
3.6 Handwashing facilities 8
3.7 Emergency eyewash/shower equipment 9
3.8 Housekeeping procedures 9

4 Personnel considerations 9

4.1 General rationale 9
4.2 Staff education and development 9
4.2.1 Qualifications 9
4.2.2 Training and continuing education 10
4.3 Health and personal hygiene 11
4.4 Attire 11
4.5 Standard precautions 13

5 Immediate handling of contaminated items at point of use 13

5.1 General rationale 13
5.2 Separation of waste and reusable items at point of use 13
5.3 Care and handling of contaminated reusable items at point of use 14

6 Transportation 14

6.1 General rationale 14
6.2 Containment 14
6.3 Transportation equipment 15
6.4 Transportation scheduling and routes 15
6.5 Transportation between buildings 15
6.6 Off-site transportation 15

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i

Single user licence only. Copying, networking and distribution prohibited.

7 Decontamination processes 15

7.1 General rationale 15
7.2 Presoaking 16
7.3 Sorting and disassembly 16
7.4 Cleaning 16
7.4.1 General 16
7.4.2 Cleaning agents 17
7.4.3 Methods of cleaning 17
7.4.4 Verification of the cleaning process 18
7.5 Microbicidal processes 18
7.5.1 General 18
7.5.2 Disinfection processes 19
7.5.3 Sterilization processes 20

8 Servicing and repair of contaminated devices in the health care facility 21

8.1 General rationale 21
8.2 Potential for exposure 22
8.3 Protective measures for service personnel 22
8.3.1 General 22
8.3.2 Education and training 22
8.3.3 Vaccination 22
8.3.4 Personal protective equipment 22
8.3.5 Work practices 23
8.4 Postexposure program 23
8.5 Devices that cannot be repaired in-house 23

9 Process performance 23

9.1 General rationale 23
9.2 Quality process 23

Annexes

A Examples of workplace design 25

B Infection transmission 34

C Selection and use of chemical disinfectants 38

D Thermal disinfection 44

E Devices returned to the manufacturer 45

F Occupational exposure to bloodborne pathogens (29 CFR Part 1910.1030) 51

G Bibliography 65

Tables

1 IES-recommended illuminance levels for work environments 8

C.1 Levels of disinfection according to type of microorganism 39

C.2 Occupational exposure limits for some chemical sterilants and disinfectants 43

Figures

A.1 Example of a work area design and work flow pattern for a sterile processing department in a typical small hospital 25

A.2 Example of a work area design and work flow pattern for a sterile processing department in a typical medium-sized hospital 26

A.3 Example of a work area design and work flow pattern for a sterile processing department in a typical regional processing center 27

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

A.4 Example of a work area design and work flow pattern for a sterile processing department 28

A.5 Example of a work area design and work flow pattern for a sterile processing department 29

A.6 Example of a work area design and work flow pattern for a sterile processing department 30

A.7 Example of an ambulatory surgery facility 31

A.8 Example of a dental facility 32

A.9 Example of a dental facility 33

B.1 The chain of infection, components of the infectious disease process 34

B.2 Bloodborne pathogen strike-through conversion chart 36

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i

Single user license only. Copying, networking, and distribution prohibited.

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 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations

© 2003 Association for the Advancement of Medical Instrumentation

Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

International designation	U.S. designation	Equivalency
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This recommended practice was developed by the AAMI Decontamination Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of this recommended practice does not necessarily mean that all committee and working group members voted for its approval.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochairs:
Victoria Hitchins, PhD
William E. Young

Members:
Bettye Beebe, Alcon Laboratories, Inc.
Trabue D. Bryans, AppTec Laboratory Services
Virginia C. Chamberlain, PhD, Hendersonville, NC
Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System, Lebanon, NJ
Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management
Charles Cogdill, Boston Scientific
Kimbrell Darnell, Bard Medical Division
Loretta L. Fauerbach, MS, CIC, Association for Professionals in Infection Control and Epidemiology
Dorothy M. Fogg, RN, BSN, MA, Association of periOperative Registered Nurses
Lisa Foster, Ion Beam Applications
James M. Gibson, Jr., JM Gibson Associates
Barbara J. Goodman, RN, BS, CNOR, Rising Sun, MD
Joel R. Gorski, PhD, NAMSA
Susan Hadfield, Canadian Standards Association
Deborah Havlik, Abbott Laboratories
Victoria Hitchins, PhD, U.S. Food and Drug Administration
Clark W. Houghtling, Cosmed Group, Inc.
Lois Jones, Cary, NC
Sue Kuhnert, STS duoTEK
Byron J. Lambert, PhD, Guidant Corporation
Sandra A. Lee, RN, STERIS Corporation
Patrick J. McCormick, PhD, Bausch & Lomb, Inc.
Thomas K. Moore, Getinge USA
Robert F. Morrissey, PhD, Johnson & Johnson
Barry F. J. Page, Garner, NC
Phil M. Schneider, 3M Health Care
Michael H. Scholla, MS, PhD, DuPont Medical Packaging Systems Inc.
Robert Sharbaugh, PhD, CIC, Hill-Rom Company
Frank Sizemore, American Society for Healthcare Central Service Professionals
Gregory O. Stecklein, MS, MSM, Cardinal Healthcare Products and Services Group
William N. Thompson, TYCO Healthcare
James L. Whitby, MA, MB, FRCP, London, Ontario, Canada
Thelma Wilcott, Becton Dickinson
Martell Kress Winters, Nelson Laboratories
William E. Young, Baxter Healthcare Corporation

Alternates:
Lina C. Bueno, Dupont Tyvek
Richard DeRisio, MS, STERIS Corporation
Joyce M. Hansen, Baxter Healthcare Corporation
Jim Kaiser, Bausch & Lomb, Inc.
Susan G. Klacik, AS, BS, International Association of Healthcare Central Service Materiel Management
Joseph J. Lasich, BS, Alcon Laboratories
Chiu Lin, PhD, U.S. Food and Drug Administration
Lisa N. Macdonald, Becton Dickinson
Ralph Makinen, Guidant Corporation
Jerry R. Nelson, MS, PhD, Nelson Laboratories
Janet Prust, 3M Health Care
James Whitbourne, STS duoTEK
William T. Young, Ion Beam Applications

Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

At the time this document was published, the **AAMI Decontamination Working Group** had the following members:

Cochairs:	Sandra A. Lee, RN Frank Sizemore
Members:	Solomon Alade, PhD, Alcon Laboratories Inc. Richard Bancroft, Albert Browne Inc. Mike Cain, Getinge USA Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System, Lebanon, NJ Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management Anthony J. DeMarinis, MS, CQA, CQM, Davol Inc./CR Bard Loretta L. Fauerbach, MS, CIC, Association for Professionals in Infection Control and Epidemiology Martin S. Favero, PhD, Advanced Sterilization Products/Johnson & Johnson Dorothy M. Fogg, RN, MA, Association of periOperative Registered Nurses Zory R. Glaser, PhD, MPH, CSPDM, Columbia, MD Steve N. Goldstine, PhD, DDS, Olympus America Inc. Barbara J. Goodman, RN, CNOR, Rising Sun, MD John Hamilton, SRI/Surgical Express Charles O. Hancock, RAC, H&W Technologies David K. Jeng, Cardinal Health Jim Kaiser, Bausch & Lomb Inc. Sandra A. Lee, RN, STERIS Corporation Martha T. O'Lone, U.S. Food and Drug Administration Barry F. J. Page, Garner, NC Charles D. Paige, U.S. Department of Veterans Affairs Frank Pescatore, Abbott Laboratories Vana Poovala, Phillips Medical Systems Matthew Roybal, Nelson Laboratories Inc. Janet K. Schultz, RN, MSN, Parker, CO Retta C. Sengstock, RN, Coram, NY Robert J. Sharbaugh, PhD, CIC, Hill-Rom Company Frank Sizemore, American Society for Healthcare Central Service Professionals Linda A. Slone, RN, CNOR, Sibley Memorial Hospital, Washington, DC James Whitbourne, STS duoTEK James L. Whitby, MA, MB, FRCP, London, Ontario, Canada Martha Young, 3M Health Care
Alternates:	Kimbrell Darnell, CR Bard Joseph R. Durbin, Abbott Laboratories Victoria Hitchins, PhD, U.S. Food and Drug Administration Susan G. Klacik, ACE, International Association of Healthcare Central Service Materiel Management Sue Kuhnert, STS duoTEK Patrick J. McCormick, PhD, Bausch & Lomb Inc. Thomas K. Moore, Getinge USA Jeff Pollis, STERIS Corporation Janet Prust, 3M Health Care Cynthia Spry, Advanced Sterilization Products/Johnson & Johnson Eugenia Stern, MBA, MS, Alcon Laboratories Inc.

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.

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

Foreword

This recommended practice was developed by the AAMI Decontamination Working Group, under the auspices of the AAMI Sterilization Standards Committee. The guidelines contained in this document are intended to help ensure that reusable medical devices are handled, transported, cleaned, and biologically decontaminated under the best possible conditions for the maximum safety and protection of patients, personnel, and the environment.

This document is the third edition of the recommended practice, which was first published in 1991 as *Good hospital practice: Handling and biological decontamination of reusable medical devices* (ANSI/AAMI ST35:1991). The second edition of the recommended practice was published in 1996 as *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings* (ANSI/AAMI ST35:1996).

This new edition provides updated recommendations concerning protective attire and standard precautions, reflects current cleaning technology, and incorporates illustrations of workplace design.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for optimum decontamination practices. It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations might not be immediately achievable. Therefore, the document should serve as a guide to desirable performance objectives, and all of the document's provisions should be considered and applied using 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 departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate departments, committees, and/or professionals (e.g., safety, infection control, hazardous materials). Policies and procedures should take into account federal, state, and local regulations; the recommendations of the Centers for Disease Control and Prevention; national voluntary standards and recommended practices; and device/equipment manufacturers' recommendations. The policies and procedures should be sufficiently detailed to enable personnel to correctly handle various devices and pieces of equipment, including the separation of reusable items from disposable items, trash and linen containment, and transport/receiving procedures. The policies and procedures should be uniform throughout a health care facility or manufacturing organization, and compliance should be monitored.

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 new data and advancements in technology. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every five 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 22201-4795.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings* (ANSI/AAMI ST35:2003), but it does provide important information about the development and intended use of the document.

Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

Introduction: Need for the recommended practice

All microorganisms in health care facilities should be considered potentially pathogenic. Realistically speaking, though, their ability to produce an infection or disease process depends on several factors, including the number and virulence of infectious organisms, the presence of a portal of entry, and the susceptibility of the host. Medical devices, instruments, and equipment that are used in patient care can become contaminated with microorganisms and must be decontaminated.

Decontamination is the process by which medical devices, instruments, and equipment are rendered safe for personnel to handle. In some cases, the decontamination process is sufficient to render the items safe for reuse in patient care. The type and level of decontamination required is determined by the circumstances of device use, the type of patient contact, and the likelihood of biological hazard to personnel.

Infection prevention is enhanced when (a) soiled supplies and equipment are correctly and safely handled and (b) reusable medical items are thoroughly cleaned. Whenever cleaning is not sufficient to render an item safe for personnel handling, the item is subjected to a subsequent microbicidal process that has been designed to provide an appropriate level of microbial lethality (kill). This process could be a disinfection process or a sterilization process. The microbicidal process might not be effective if soil has not been first removed by cleaning. When used for decontamination purposes, a microbicidal process does not necessarily make an item safe for patient use, because the level of microbial kill might not be sufficient for the intended use (as in the case of surgical instruments needed for sterile procedures).

Adherence to the principles of infection control will help prevent the spread of potentially infectious or disease-producing microorganisms from one person to another and will help ensure that all items are safe for handling during inspection, assembly, preparation, and packaging. In addition, adherence to those principles is one of the essential factors in achieving effective terminal sterilization processing, when appropriate for a particular reusable item.

The selection of an appropriate decontamination method is complex because of the huge variety of reusable items and the wide range of processes for achieving various levels of decontamination. There are diverse and often conflicting recommendations for handling supplies and equipment and for controlling biological hazards through decontamination methods. These diverse recommendations have been provided to health care personnel by professional organizations, government agencies, manufacturers of decontamination products and equipment, medical device manufacturers, and speakers/consultants. There is clearly a need for consensus guidelines, with supporting rationale, for decontamination processing techniques. The objective of this recommended practice is to provide guidelines that will (a) help reduce the risk of cross-infection by pathogenic microorganisms to patients, personnel, and other persons, (b) assist in the development of decontamination procedures based on knowledge and scientific data, and (c) help ensure that all reusable medical devices are handled, transported, cleaned, biologically decontaminated, and reprocessed or examined under the best possible conditions for maximum safety.

The provisions of this recommended practice should be reviewed by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate departments, committees, and/or professionals (e.g., infection control, safety, and hazardous materials).

© 2003 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST35:2003

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

© 2003 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST35:2003
Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings

1 Scope

1.1 General

This recommended practice primarily addresses procedures for the safe handling of contaminated items and biological decontamination methods for reusable items between individual patient uses. The terms “contaminated” and “contamination,” as used here, apply to all reusable items that have been opened and/or used in any patient care procedure. The biological decontamination process includes thorough cleaning and, whenever necessary for personnel or patient safety, appropriate application of a microbicidal process (disinfection or sterilization).

NOTE 1—In the context of this recommended practice, the term “sterilization” refers to a microbicidal process used to decontaminate items posing significant biological hazards to personnel. A “terminal sterilization” process is required for decontaminated items that will be reused in a sterile procedure.

NOTE 2—For the purposes of this recommended practice, “health care facilities” means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term “hospital” is sometimes used; in every instance, the term encompasses all other health care facilities.

1.2 Inclusions

This recommended practice specifically addresses

a) design criteria for decontamination areas;

b) staff qualifications, education, and other personnel considerations;

c) immediate handling of contaminated items at the point of use;

d) transport of contaminated items; and

e) decontamination processes.

Definitions of terms and a bibliography also are provided in this recommended practice, as well as annexes providing supplementary information on decontamination area design (annex A); the principles of infection transmission (annex B); the selection and use of chemical disinfectants (annex C); thermal disinfection (annex D); the safe handling and decontamination of medical devices returned to medical device manufacturers for servicing, repair, or failure investigation (annex E); and the Occupational Safety and Health Administration (OSHA) bloodborne pathogen regulation (29 CFR 1910.1030) (annex F).

1.3 Exclusions

Excluded from this recommended practice are procedures and techniques for handling contaminated reusable laboratory items, food service items, reusable textiles (laundry), and items assigned to a patient for the length of stay (e.g., bedpans, thermometers). In addition, this recommended practice does not address decontamination of hemodialysis machines, hemodialyzers, or hemodialyzer blood tubing; nor does it discuss the use of dry heat for decontamination purposes or terminal sterilization of reusable medical items. Terminal sterilization by saturated steam is covered in ANSI/AAMI ST37, ANSI/AAMI ST42, and ANSI/AAMI ST46. Terminal sterilization by ethylene oxide (EO) is covered in ANSI/AAMI ST41 and Danielson (1998). Terminal sterilization by dry heat is covered in ANSI/AAMI ST40. The decontamination of hemodialysis machines, hemodialyzers, and hemodialyzer blood tubing is addressed in ANSI/AAMI RD5, ANSI/AAMI RD47, and AAMI TIR6, respectively. The processing of reusable surgical textiles is covered in ANSI/AAMI ST65.

© 2003 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST35:2003

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single-user license only. Copying, networking, and distribution prohibited.

2 Definitions, symbols, and abbreviations

For the purposes of this recommended practice, the following definitions apply.

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

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

2.2 biofilm: Matrix that contains cells, living and dead, as well as polysaccharide (sometimes referred to as glycocalyx), and that is exuded by microorganisms when they are growing in water or water solutions or *in vivo* (e.g., the bloodstream). Biofilm prevents antimicrobial agents such as sterilants, disinfectants, and antibiotics from reaching the microorganisms.

2.3 CDC: Centers for Disease Control and Prevention.

2.4 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

2.5 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.

2.6 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.

2.7 disinfection: Destruction of pathogenic and other microorganisms by thermal 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.

2.8 engineering controls: According to OSHA, “controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace” (29 CFR 1910.1030).

NOTE—More generally, the term also refers to controls that reduce or remove other workplace hazards such as exposure to toxic chemicals.

2.9 EPA: Environmental Protection Agency.

2.10 exposure control plan: According to OSHA, “a written [plan] designed to eliminate or minimize employee exposure” (29 CFR 1910.1030).

2.11 FDA: Food and Drug Administration.

2.12 high-level disinfection: Process capable of killing all microorganisms with the exception of high numbers of bacterial spores.

2.13 intermediate-level disinfection: Process capable of killing the tubercle bacillus, vegetative bacteria, most viruses, and most fungi, but not necessarily bacterial spores.

2.14 liquid-proof material: Material that prevents the penetration of liquids and microorganisms.

2.15 liquid-resistant material: Material that inhibits the penetration of liquids.

2.16 low-level disinfection: Process capable of killing most bacteria, some viruses, and some fungi, but not the tubercle bacillus or bacterial spores.

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

a) diagnosis, prevention, monitoring, treatment, or alleviation of disease;

Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

c) control of conception;

and which does not achieve its principal 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.

2.18 microbicidal process: Process designed to provide a particular level of microbial lethality (kill).

NOTE—Depending on the level of decontamination needed, this process could be a disinfection process or a sterilization process. The type and level of microbial kill achieved depends on factors such as the type and population of microorganisms present, the type of antimicrobial agent, the concentration of the antimicrobial agent, the exposure time, and the exposure temperature. When used for decontamination purposes, a microbicidal process does not necessarily yield an item that is safe for patient use.

2.19 minimum recommended concentration (MRC): Minimum concentration at which the manufacturer tested the product and validated its performance.

NOTE—The term "minimum effective concentration" (MEC) is sometimes used interchangeably with "minimum recommended concentration."

2.20 nonrestricted area: Area where traffic is not limited and dress attire is not prescribed.

2.21 occupational exposure: According to OSHA, "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties" (29 CFR 1910.1030).

NOTE—More generally, the term also refers to potential contact with other hazardous substances or conditions during the performance of an employee's duties.

2.22 OSHA: Occupational Safety and Health Administration.

2.23 pasteurization: Disinfection process using hot water at temperatures of 65 °C to 77 °C (150 °F to 170 °F) for a contact time of at least 30 minutes (min).

2.24 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).

2.25 prions: Virus-like infectious agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jakob disease (CJD) in humans. Prions are thought to differ from viruses by containing neither DNA nor RNA, only protein. They are extremely resistant to inactivation by heat and disinfecting agents. (Block, 2001)

2.26 pyrogen: Fever-producing substance.

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

2.27 restricted area: Area where access and traffic are limited to authorized personnel and dress attire might be prescribed.

2.28 reusable medical device: Devices intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

NOTE—Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

2.29 sanitization: According to Block (2001), "the act of reducing the number of bacterial contaminants in the environment to a safe or relatively safe level as may be judged by public health requirements or at least to a significant degree where public health standards have not been established. Block (1983) qualifies the definition of a sanitizer in that such an agent is ordinarily used on an inanimate surface."

2.30 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."

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user licence only. Copying, networking and distribution prohibited.

2.31 standard precautions: 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 medical devices, 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.

2.32 sterile/sterility: State of being free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. See "sterilization."

2.33 sterility assurance level (SAL): Probability of a viable microorganism being present on a product after sterilization.

NOTE 1—SAL is normally expressed as 10^{-n}.

NOTE 2—A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item. It is generally accepted that a SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers). A SAL of 10^{-3} (a one in a thousand chance of a surviving microorganism) is considered acceptable for items not intended to come into contact with compromised tissue.

2.34 sterilization: Process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

2.35 terminal sterilization: Validated process whereby product within its primary package is sterilized.

2.36 transmission-based (enhanced) 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 (enhanced) precautions: airborne precautions, droplet precautions, and contact precautions.

2.37 work practice controls: According to OSHA, "controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique)" [29 CFR 1910.1030].

3 Design considerations

3.1 General rationale

This section provides guidelines for the design and maintenance of the decontamination area to facilitate effective and efficient processing, minimize environmental contamination, and promote the safety of personnel who handle contaminated items and perform the decontamination process.

NOTE—Detailed recommendations for the design of sterile processing departments are provided in ANSI/AAMI ST46.

3.2 Centralization of decontamination

Centralizing decontamination activities is usually safer and more cost-effective than replicating them in several areas of the health care facility. It could be necessary, however, for decontamination activities to be performed in several areas within the health care facility. If so, the work practices recommended in this document should be consistently followed throughout the health care facility.

Rationale: Decontamination is a multistep process requiring environmental controls (e.g., controlled air changes, exhaust ventilation, temperature, and humidity, as recommended in 3.4); appropriate equipment and supplies; adequate space; qualified, competent personnel who are provided with ongoing training and personal protective equipment (PPE); and monitoring for quality assurance.

3.3 Design criteria

The basic concepts of work flow should be defined during initial planning or remodeling of the decontamination processing area(s). This planning should include projections for the inventory of cleaning supplies (including disposables); the space needed for storage, handling, and/or disposal of PPE; and the decontamination equipment

© 2003 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST35:2003
Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

and transportation systems. The functional work areas should be designed accordingly, taking into account the engineering controls required by OSHA. The following are some of the key issues to be considered.

a) Will decontamination be centralized (performed in one department) or decentralized (performed in several departments, such as the operating room, labor/delivery suite, central service department, and medical device reprocessing room), or will a combination of approaches be used?

b) Which departments will be served?

c) How will contaminated items be contained at the point of use?

d) Will there be a need for emergency or short-term processing at the point of use? If so, what kind of processing will take place at the point of use?

e) What type of transport system (i.e., types and sizes of case carts, soiled pickup carts, elevators/lifts, automated systems) will be used to deliver contaminated items to the decontamination area?

f) How will transportation carts be cleaned between uses?

g) Where will reusable medical devices, case carts, and so forth be received and held in the decontamination area before processing?

h) Will a cart washer be installed?

i) Will a steam gun/room be needed for other patient care equipment (with appropriate space, ventilation, drainage, and nonskid flooring)?

j) Will rigid sterilization container systems be used? If so, what will be the impact on manual and mechanical processing, equipment utilization, and the space needed to queue items?

k) Will automated systems be used to feed baskets of instruments, basins, utensils, and so forth into mechanical washers? If so, how much additional space will be needed?

l) Will the decontamination process be performed manually, mechanically, or by a combination of methods?

m) What types and quantities of reusable supplies, instruments, and equipment will be decontaminated?

n) Where will reusable patient-care equipment be decontaminated? What level of decontamination will be required for each type of patient-care equipment?

o) What inventory levels of cleaning supplies will be maintained in the decontamination area?

p) What provision will be made to separate soiled, in-use bottles of detergents, disinfectants, and other such supplies from extra supplies in storage so that personnel not wearing PPE can acquire the supplies for other areas without being exposed to contaminated items?

q) What types of PPE will be needed? What will be the storage requirements? Which equipment will be reusable and what care will the reusable equipment require? Which PPE will be disposable and how will that disposal be handled?

r) Where will housekeeping supplies dedicated for use only in the decontamination area be stored?

s) How much adjacent space will be needed for personnel to don and remove PPE?

t) How many sinks will be needed for handwashing? What type of sinks? Where will they be located? How will the sinks be separated from those used for decontamination processes?

u) What provision will be made for the disposal of liquid and solid body wastes?

v) Will any projected changes in the health care delivery system affect the space, equipment, and processing needs of the decontamination area? (They should be considered now to simplify and accommodate expansion in the future.)

w) What environmental controls will be required? (Environmental conditions (temperature and humidity) should be displayed accurately within the decontamination area.)

x) What provision must be made for emergency power backup?

y) Where will the Material Safety Data Sheets (MSDSs) for decontamination chemicals be stored?

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

z) Will compressed air/forced air be needed? Where will it be located?

aa) What is the quality of water required for the various decontamination processes (manual and mechanical)?

NOTE—A source of treated water (e.g., deionized, reverse-osmosis-(RO)-treated, distilled) should be considered for appropriate locations.

bb) Can a pass-through system be used so that equipment/instruments can be passed through from the decontamination room to the clean areas without entering a hallway?

cc) Where will the manufacturer's instructions for cleaning be located?

dd) What provisions will be made for linen and trash storage/disposal?

ee) What are the air-handling/ventilation requirements for the general area and the various manual and mechanical decontamination processes?

ff) Is there a need for a communication system? Which areas should be included?

gg) Will a lighted magnifying glass be needed? Where will it be located?

hh) Will an ultrasonic cleaner be needed? Where will it be located?

ii) Will an area be required for the collection of disposable medical devices to be sent to a third-party reprocessor?

jj) Will automatic testing equipment be needed (e.g., leak testers, suction machines)? Where should the equipment be located?

kk) Should vertical soaking containers be considered? Where should they be located?

Annex A provides examples of work area design and workflow patterns in health care facilities of various types and sizes.

NOTE—All figures in annex A illustrate general principles and should not be interpreted as endorsements of specific designs.

Rationale: Because decontamination is the first and most critical step in the reprocessing of reusable medical devices, all of these factors should be considered in the design of the decontamination workplace to ensure consistency in practices.

3.4 Work area design

3.4.1 Physical layout

Ideally, the decontamination area should be physically separated from all other areas of the processing department and accessible from a service corridor. In small health care facilities, clinics, and dental/medical offices, it might not be possible to physically separate the decontamination area. In such cases, procedural barrier separation, while not generally desirable, could be adequate, provided that work practices prevent splashing, the production of aerosols, and contamination of clean items and work surfaces, and provided that work practices promote the changing of PPE when personnel leave the decontamination area and enter clean areas. In surgical facilities, the decontamination area should be physically separated from other areas by means of doors, service windows, and/or pass-through equipment. (For example, the area where flexible endoscopes are decontaminated should be separate from the endoscopic procedure area.) Automatic doors are preferable, since most of the traffic will consist of carts. When procedural barrier separation is used, it is essential that ventilation/air-handling systems move air from the clean side of the room to the soiled processing side of the room and not the reverse (see 3.4.4).

The need for floor drains depends on the potential for liquid spillage from decontamination procedures and equipment. Floor drains should be properly placed and large enough to accommodate any fluid or water runoff. Sinks should be large enough to contain large utensils and instruments, and there should be enough sinks to accommodate concurrent soaking, washing, and rinsing. An ideal decontamination sink is approximately 36 inches from the floor, 10 inches deep, and wide and long enough to allow a tray or container basket of instruments to be placed flat for pretreatment or manual cleaning. Provision should be made to accommodate employees of varied heights. Forced air, faucets or manifold systems for flushing lumened devices, and, if necessary, a source of treated water (e.g., deionized water, RO-treated water, distilled water) should be provided at the sink. Sinks should have attached counters or adjacent work surfaces on which to place soiled and clean items separately. Lights and other fixtures should be recessed and sealed to prevent the accumulation of dust or soil and to facilitate cleaning.

Ergonomic factors affecting worker safety and comfort should be considered when designing work spaces. For example, counters and work surfaces should be positioned at heights that take into account the average height of

Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

the employees and the tasks to be performed at each location. Sinks should not be so deep that personnel must bend over to clean instruments. To the extent possible, employees should avoid lifting and carrying items. Therefore, there should be adequate space to maneuver, queue, and unload carts or other transportation means at times of average daily peak work load.

Rationale: The concentration of airborne microbial and particulate contamination is likely to be high or elevated in the decontamination area because of the presence of grossly soiled items, manual cleaning that produces aerosols, and, in some facilities, trash and linen handling from surgery case carts. Contamination also can occur when personnel with contaminated hands indiscriminately touch environmental surfaces, other devices, or other personnel. Physical enclosure of the decontamination area is recommended because contaminated aerosols, droplet nuclei, and dust particles can be carried from dirty to clean areas by air currents. Human factors engineering during the design phase could assist in preventing worker injury.

3.4.2 Functional work flow patterns

Work flow patterns should be designed to ensure that contaminants are contained and employee exposure to bloodborne and other disease-producing organisms is minimized. Work flow patterns also should be designed so that items are moved progressively from being contaminated to being safe to handle. Of particular importance are the locations of elevators used to transport soiled items, elevators used to transport clean items, case cart queuing and unloading areas, trash and linen receptacles, and sorting areas. Provision should be made for the separation of contaminated items from items being removed from mechanical processing equipment and for the cleaning of transport carts. Processing equipment that takes items from the decontamination area, mechanically processes them, and then automatically unloads them into the clean side is recommended. Pass-through windows, at equal counter height and going from the decontamination area to the clean side, also are recommended.

There should be functionally separate areas within the decontamination area for items that will require additional processing after decontamination and before patient reuse, versus items that will not require additional processing. Receiving areas for surgical instruments and other devices requiring terminal sterilization after decontamination should be strictly separated from receiving areas for instruments and devices for which the decontamination process incorporates disinfection procedures and there is no need for additional disinfection or sterilization before patient use.

Rationale: Adherence to these functional design recommendations helps contain potential contaminants within a particular portion of the decontamination area and thus helps prevent cross-contamination or recontamination. Segregation of contaminated items from items being removed from mechanical process equipment is necessary to protect the processed items (e.g., flexible endoscopes, respiratory therapy devices) from recontamination. Similarly, there is a significant risk of recontamination if receiving areas for items requiring different methods of reprocessing are not separated.

3.4.3 Ceilings, floors, walls, and work stations

Materials that will withstand daily or more frequent wet vacuuming or washing should be used in the construction or covering of wall surfaces, floors, and work stations. Floors and drains should be designed to ensure good drainage. Materials used for wall surfaces and ceilings should not be of a particulate- or fiber-shedding type.

Rationale: The floor, walls, and work stations of the decontamination area are subject to spills and splashing and must be regularly cleaned to control microbial contamination. Accordingly, it is necessary that the materials used in constructing or covering these surfaces be capable of withstanding frequent cleaning and not be adversely affected by the chemical agents typically used for cleaning. Ceilings and wall surfaces should be constructed of nonshedding materials to minimize the potential for airborne particulates which can carry disease-producing microorganisms.

3.4.4 Ventilation

Air should flow into the decontamination area from adjoining clean spaces (by negative pressure) and be exhausted to the outside. There should be no fewer than 10 air exchanges per hour. Engineering monitoring and maintenance of environmental control systems should be performed periodically and documented.

Rationale: Ventilation patterns affect the spread of potentially dangerous microorganisms. Control of environmental contaminants and product bioburden is essential to ensure the effectiveness of the subsequent sterilization process. The recommended air flow pattern (i.e., air flowing out of clean areas into “dirty” areas) contains the contaminants within the decontamination area and minimizes the possibility of air currents carrying contaminants from the decontamination area to clean areas. Control of environmental contaminants and product bioburden is essential to ensure the effectiveness of the subsequent sterilization process. AIA (2001) recommends 6 air exchanges per hour in the decontamination area. However, an air exchange rate of 10 air exchanges per hour was judged by the AAMI committee to be the minimum necessary to effectively reduce environmental contamination by means of air dilution. In addition, the AAMI committee notes that AIA (2001) does recommend 10 air exchanges per hour for other soiled

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

areas within health care facilities, that similar water and steam considerations apply to both the decontamination area and the sterilization area, and that AIA (2001) recommends 10 air exchanges per hour for the latter area.

3.4.5 Temperature and humidity

The temperature in the decontamination area should be controlled to between 16 °C and 18 °C (60 °F and 65 °F). Relative humidity should be controlled to a range of 30 % to 60 %. Free-standing fans are not permitted. Doors should not be propped open and windows should not be opened. Temperature and humidity ranges should be documented daily.

Rationale: The work area should be cool enough, with a comfortable humidity level, for personnel to be able to wear PPE. The temperature range recommended here is lower than that recommended by AIA (2001), because the AAMI committee judged that comfort is a particular consideration in the decontamination area, where PPE is worn for long periods of time and temperatures suitable for general work areas may be uncomfortably hot. In addition to comfort considerations, relative humidities higher than those recommended can create an environment conducive to microbial growth, especially molds, and thus increase the overall bioburden.

3.4.6 Lighting

Adequate lighting at work surfaces should be provided in accordance with the engineering practices outlined in Rea (1993), which describes the recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (Table 1).

Rationale: Successful decontamination is an essential part of the reprocessing function. Personnel must be able to see clearly in order to disassemble, reassemble, and inspect the cleanliness of the devices that they are processing.

Table 1—IES-recommended illuminance levels for work environments

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 footcandles)	750 lux (75 footcandles)	1000 lux (100 footcandles)
Detailed inspection	1000 lux (100 footcandles)	1500 lux (150 footcandles)	2000 lux (200 footcandles)
Sink areas	500 lux (50 footcandles)	750 lux (75 footcandles)	1000 lux (100 footcandles)
General work areas	200 lux (20 footcandles)	300 lux (30 footcandles)	500 lux (50 footcandles)
Processed storage	200 lux (20 footcandles)	300 lux (30 footcandles)	500 lux (50 footcandles)

3.5 Traffic control

Traffic in areas where decontamination is performed should be restricted to authorized personnel. There should be controlled access. Criteria for authorized entry and attire when entering, working within, and exiting from the decontamination area should be specified in departmental, facility, or office policies and procedures. The responsibility and authority for enforcing traffic control policies, as well as methods of compliance, should be specified. Doors should be used to physically separate the decontamination area from the hallway and clean areas.

Rationale: Decontamination might be performed at the point of use and in designated decontamination areas. It is important that personnel, visitors, and patients be protected from airborne contaminants and the microorganisms present on contaminated items in the decontamination area. Consequently, good traffic control is essential.

3.6 Handwashing facilities

Handwashing facilities should be conveniently located and designed to allow good handwashing practices. They should be located in or near all decontamination areas and be separate from sinks used in cleaning or rinsing items to be decontaminated. Handwashing facilities also should be located in all personnel support areas (e.g., toilets, lounges). Personnel should be instructed regarding handwashing techniques. The installation of hands-free-operated equipment (e.g., foot controls, electronic sensors) for use with sinks, towel dispensers, and soap dispensers should be considered during the design of new facilities. If hands are not visibly soiled, hands may be

© 2003 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST35:2003
Documents Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

decontaminated with alcohol-based, waterless, hand hygiene agents, which should be made available to health care personnel.

Rationale: Adequate handwashing facilities will promote hand decontamination by appropriate handwashing. Hands should be washed when visibly soiled. The use of alcohol-based, waterless agents is an effective means of hand decontamination when hands are not visibly soiled. Such agents have been shown to decrease dryness and irritation associated with traditional handwashing. Additionally, increased availability of these agents in the work area can contribute to increased compliance with hand decontamination. Therefore, both traditional handwashing and hand hygiene should be encouraged to reduce the risk of transmission of microorganisms via the hands. Hands should be decontaminated after gloves are removed for any reason, after the removal of other PPE, and in accordance with good personal hygiene practices and departmental policy. Hands-free-operated equipment helps personnel avoid touching faucet handles, towel dispensers, or soap dispensers with their hands, thus minimizing microorganism transfer among patients, personnel, and inanimate objects.

3.7 Emergency eyewash/shower equipment

Emergency eyewash/shower equipment should be located within 10 seconds' travel time of all chemical usage locations; for a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard. In addition, a 15-min supply of continuous free-flowing water is required, and the hands must be free to hold the eyelids open. The equipment should be selected, installed, and maintained to meet the performance standards established by the American National Standards Institute (ANSI, 1998). Procedures for testing and documenting the performance of the equipment should be developed and followed. Employees should be instructed in the proper use and maintenance of the emergency equipment. Following the emergency treatment, employees should seek medical attention.

Rationale: Emergency eyewash and shower equipment should be readily accessible in order to provide first aid to employees exposed to injurious chemicals and materials. Immediate flushing of exposed tissue is recommended to reduce the risk of serious injury. 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 prevent contamination. See also OSHA's eye and face protection standard (29 CFR 1910.133), OSHA's medical and first aid standard (29 CFR 1910.151), and ANSI (1998).

3.8 Housekeeping procedures

There should be at least daily cleaning and disinfection of horizontal work surfaces. Horizontal work surfaces should be cleaned and disinfected at the end of each shift and whenever they become visibly soiled. Floors should be cleaned and disinfected at least daily; if the floors are waxed, they should be stripped regularly according to facility or office policy. Other surfaces, such as walls and storage shelves, should be cleaned on a regularly scheduled basis and as needed for spot cleaning of soiled areas. All spills should be treated as soon as possible; cleaning and disinfection, as appropriate, should be performed in compliance with facility infection control policies.

Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from "dirty" to "clean" areas and surfaces. Separate housekeeping facilities and equipment should be provided for the decontamination area.

Rationale: Cleaning and disinfection remove soil and reduce the number of microorganisms, thereby reducing the possibility of transmission of infections.

4 Personnel considerations

4.1 General rationale

This section provides guidelines for personnel qualifications, staff development, and education, as well as minimum criteria for personnel health, personal hygiene, and attire. All aspects of decontamination of reusable medical devices should be supervised and performed by competent personnel. The other personnel considerations covered in this section are essential to minimizing bioburden, controlling environmental contamination, and promoting worker safety.

4.2 Staff education and development

4.2.1 Qualifications

4.2.1.1 Supervisory personnel

All handling, cleaning, and biological decontamination of reusable medical devices should be performed under competent supervision. Personnel assigned to supervisory functions should be prepared for this responsibility by education, training, and experience. Minimum supervisory qualifications include

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only. Copying, networking, and distribution prohibited.

a) successful completion of a central service management certification examination and maintenance of this certification throughout the supervisory term;

NOTE—Information concerning certification of central service managers and processing technicians can be obtained from the Certification Board for Sterile Processing and Distribution (Route 31 North Office Center, 121 State Highway, Suite 700, Flemington, NJ 08822; 800-555-9765), the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078), or the National Health Information Center (P.O. Box 1133, Washington, DC 20013).

b) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work;

c) participation in formal orientation and ongoing educational programs (e.g., educational seminars, personnel and material management programs, and courses directly related to the position, with special emphasis on receiving, handling, cleaning, decontamination, and principles of infection control); and

d) demonstration of comprehensive knowledge of OSHA regulations pertaining to occupational exposure to bloodborne pathogens (29 CFR 1910.1030), including the specified methods of compliance such as an exposure control plan, the use of standard/transmission-based (enhanced) precautions, and engineering and work-practice controls.

Rationale: Decontamination of reusable medical devices is a complex process requiring supervision by competent personnel with relevant health care experience, especially in cleaning methods and products, containment of contaminated items, sterilization and disinfection methods, infection control, and standard/transmission-based (enhanced) precautions. Standard/transmission-based (enhanced) precautions address airborne, droplet, and contact issues. Compliance with OSHA regulations will lower the incidence of occupational exposure to bloodborne and other pathogens. Certification is a recognized method of initially determining competency.

4.2.1.2 Decontamination personnel

The responsibility for handling, cleaning, and decontaminating reusable medical devices should be assigned to qualified individuals who have demonstrated competence in all aspects of decontamination, including sorting, disassembly, manual and mechanical cleaning methods and microbicidal processes, equipment operation, standard/transmission-based (enhanced) precautions, and engineering and work-practice controls. The competence of individuals to perform assigned tasks should be documented.

NOTE—It is recommended that all personnel performing decontamination activities be certified as a condition of employment. At a minimum, all such personnel should successfully complete a central service certification examination within two years of employment and maintain that certification throughout their employment.

Rationale: Protection of the patients, employees, and other individuals in the hospital environment depends on the implementation of procedures designed to reduce the risk of exposure to potentially pathogenic microorganisms. Documentation of competence provides verification of qualifications and training in the workplace, as required by regulatory and accrediting agencies. Standard/transmission-based (enhanced) precautions address airborne, droplet, and contact issues.

4.2.2 Training and continuing education

Personnel engaged in decontamination processing and anyone else who could potentially be exposed to bloodborne pathogens should receive initial orientation and on-the-job training including, but not limited to, instruction on the care and handling of devices, cleaning methods, disinfecting agents, containment of contaminated items, prevention of cross-contamination, standard/transmission-based (enhanced) precautions (see 4.5), the use of required PPE, the importance of vaccinations as protective measures, basic microbiological principles, safety precautions, potential hazards, transportation, equipment operation, parameters of microbicidal processes, and the health care facility's infection control policies and procedures, especially those pertaining to standard/transmission-based (enhanced) precautions and engineering and work-practice controls. In addition, continuing education should be provided at regular intervals to review and update worker knowledge and skills. Education and training materials and information are available commercially (e.g., from manufacturers of PPE, exposure control devices, and disinfectants); in addition, OSHA has educational materials available for loan. When a new medical device or piece of equipment is introduced into the system, the staff should receive inservice training in decontamination protocols in accordance with the recommendations of the device manufacturer and equipment manufacturer. In addition, the staff should receive periodic refresher training on current devices. All orientation, on-the-job, and inservice training should be documented.

Personnel training and continuing education should specifically address the decontamination of reusable medical devices. All training and continuing education should be documented.

Documents Document Sharing Hub

Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i

Single user license only. Copying, networking, and distribution prohibited.

Rationale: Orientation training and on-the-job training establish the worker's base of knowledge, while continuing education increases knowledge and skills. Education and training are the most important aspects of any program intended to protect employees from a potential safety hazard. Without it, the employee might not recognize unsafe conditions or work practices and might not know how, when, or why to employ protective measures. Hospital policies and procedures are a necessary part of any education and training program, and all personnel should be familiar with and adhere to these policies and procedures. Documentation of training, continuing education, and maintenance of competency is required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 2000). Certification is a recognized method of determining initial competency. It is necessary to provide instructions to decontamination personnel regarding the processing recommendations of specific device and equipment manufacturers.

4.3 Health and personal hygiene

Written policies on personal hygiene should be developed, approved by infection control, the office safety manager, or the designated person in charge of training, and communicated to employees. Handwashing procedures should be defined. Hair, body, and nails should be clean at all times. The use of nail polish or artificial nails should be avoided. Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the institution's infection control committee, the department should establish a written policy on the reporting, treatment, and disposition of employees who are injured on the job or are at risk of acquiring or transmitting infections. Exposures to bloodborne diseases should be handled in accordance with OSHA regulations and current Centers for Disease Control and Prevention (CDC) recommendations.[1] Personnel who can potentially come into contact with items contaminated with blood or body fluids (occupational exposure) should be encouraged to accept hepatitis B immunization. Any employee who declines immunization should sign the hepatitis B vaccine declination statement required by OSHA.

Rationale: Careful attention to employee health, safety, and personal hygiene will minimize the potential for disease transmission. Nail polish can flake off, and the flakes can get into items being prepared. Artificial nails can promote the growth of fungus under the nails. Vaccinations provide backup protection when there has been a failure in work practices or an unexpected event occurs. OSHA requires that the hepatitis B vaccine be made available to workers who could encounter bloodborne pathogens in performing their jobs. Depending on the situation, vaccination against other diseases, not necessarily bloodborne, could be appropriate.

4.4 Attire

All personnel working in the decontamination area should wear clean, facility-provided uniforms that are donned at the facility. Attire should be changed daily, or immediately if it becomes wet, grossly soiled, or visibly contaminated by blood or body fluids. If reusable, uniforms visibly contaminated by blood or body fluids must be laundered in the laundry facility/area designated by the health care facility for the decontamination of reusable surgical textiles (see ANSI/AAMI ST65). Reusable uniforms that are not visibly contaminated by blood or body fluids should be laundered in accordance with facility policy. All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering or hood. Neither jewelry nor wristwatches should be worn.

Clean shoes or boots, to be worn only in the hospital, should be maintained by personnel. The surface touching the floor should be made of a nonskid material or with a nonskid design. Shoes or boots should be durable enough to prevent injury if an item drops on the foot. Disposable shoe covers should be liquid-resistant or, if there is a potential for soaking, liquid-proof. Disposable shoe covers should be removed and discarded when the employee leaves the decontamination area and replaced by clean shoe covers when the employee returns.

The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) requires that each facility have in place an exposure control plan that outlines the potential hazards that may be encountered while on the job. The plan must also identify engineering controls, work practices, and/or preventive medical care by which the safety and health of employees are to be maintained. In the decontamination area, these measures will include the use of PPE. In addition to the attire recommended above, general-purpose utility gloves, a liquid-resistant covering with sleeves (for example, a backless gown, jumpsuit, or surgical gown), a surgical face mask, and eye protection should be worn at all times in the decontamination area.

[1] Information on CDC recommendations regarding exposures to bloodborne diseases can be obtained by checking the CDC Web site at <http://www.cdc.gov/ncidod/hip/guide/phspep.htm> or calling CDC at 1-800-311-3435.

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST35:2003, Safe handling and biological decontamination of reusable medical devices in health care facilities and i
Single user license only, copying, networking, and distribution prohibited.