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

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.*

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

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

Printed in the United States of America

ISBN 1–57020–193–5

Contents

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

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

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

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.

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.

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).

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.

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;

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."

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

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?

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

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

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

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

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.

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.

Reusable gloves, aprons, and eye protection devices should be cleaned at least daily. If their integrity is compromised, they should be discarded. Torn gloves should be replaced immediately after appropriate handwashing. Items worn or used in the decontamination area should be regarded as contaminated. Before leaving the decontamination area, employees should remove all PPE, being careful not to contaminate the clothing beneath or their skin, and wash their hands. Appropriate areas should be provided for donning and removing PPE.

NOTE—The protective clothing should be made of liquid-proof materials if there is a possibility that attire can become soaked with blood or other potentially infectious material (as when items are being washed by hand).

Rationale: Contaminated instruments and other medical devices are sources of microorganisms that could invade personnel through nicks, cuts, or abrasions in skin or contact with the mucous membranes of the eyes, nose, or mouth. Appropriate, clean attire will minimize the potential for employee exposure to bloodborne and other disease-producing organisms; it also minimizes the introduction of microorganisms and lint from personnel to items being processed and the environment. Controlled laundering of garments visibly contaminated by blood or body fluids reduces the risk of transferring pathogenic microorganisms from the health care facility to home and family. The question of where nongrossly contaminated garments should be laundered is currently unresolved; there is no scientific data supporting a mandate for either facility or home laundering. Thus, it is necessary for each health care facility to establish its own policy. When deciding whether to allow home laundering, the facility should carefully consider the degree to which the requirements for clean attire can be met by workers and policed by managers. Minimum criteria for home laundering (Garcia, 2001) include

— As required by OSHA, uniforms with visible blood or body fluids must be laundered by the health care facility, not at home.

— Home laundering should utilize an automatic washer and hot-air dryer.

— While not absolutely necessary, the use of hot water (110 °F to 125 °F) is recommended in order to assist in the inactivation of microorganisms.

— Chlorine bleach should be used unless the manufacturer specifically recommends against it on the garment label. If chlorine bleach is contraindicated, then oxidizing bleaches such as those containing hydrogen peroxide should be used.

— As a matter of good personal hygiene, hands should be washed after placing laundry in the washer.

— Detergent should be used according to the manufacturer's recommendations.

— Uniforms should not be laundered with underwear, since underwear is a significant source of microorganisms.

— To facilitate removal of soil and microorganisms, uniforms should be completely submerged in the washer throughout the wash and rinse cycles.

— The door/lid of the washing machine should be kept clean and sanitary in order to reduce the possibility that laundered clothing will be contaminated upon removal from the washer.

Jewelry should not be worn because it is not easily or routinely cleaned daily, it can harbor microorganisms, and it can become dislodged and fall into processed items. Wristwatches and rings on fingers, in particular, can catch on equipment or instrumentation, causing personal injury or damage to the item.

Wearing heavy-duty, waterproof gloves while handling contaminated items greatly decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross-contamination. Gloves do not offer absolute protection, however, because they can develop small leaks due to the stresses of the cleaning process (DeGrott-Kosolcharoen and Jones, 1989); handwashing prevents any further contamination of the worker or environment. The style of glove used should prevent employee contact with contaminated water. (For example, gloves that are too short or lack cuffs allow water contact when the arms move up and down.) General-purpose utility gloves may be decontaminated and reused but should be discarded if there is evidence of deterioration (e.g., punctures, peeling, cracking). When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier. See also U.S. Food and Drug Administration (1993b).

Surgical face masks limit transfer of microorganisms to and from the respiratory tracts of personnel who are cleaning contaminated items. Eye protection reduces the risk of eye contact with microorganisms and eye injury from hazardous chemical agents. Splash and aerosols can come in contact with the eye from any direction, including settling out of the air from above under the influence of gravity. Liquids can act as vehicles for the transfer of microorganisms from soiled materials and from the skin of personnel; therefore, wet surgical attire should be considered contaminated. See also AAMI TIR11.

Under OSHA regulations, some discretion is provided for the use of masks and eye protection. However, the committee feels that these protective devices should be worn any time that biohazardous materials are being

handled if exposure is not prevented by engineering controls (such as the use of pneumatic tubes with plastic shielding for sorting soiled laundry). Taking protective devices on and off can itself be a source of contamination and thus should be minimized. Also, a face mask is considered contaminated upon use; it can promote the spread of microorganisms if it is worn hanging around the neck, stuffed into a pocket, or perched on the forehead.

4.5 Standard precautions

Standard precautions are intended to supplement, not replace, infection control practices such as handwashing and wearing PPE to avoid contact with contaminated items, blood, or body fluids. Because it is not possible to specify a protective barrier that is appropriate for every individual situation that can occur, some judgment is required on the part of the employee. The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) includes the following requirements:

— Precautions must be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).

— In general, contaminated needles should not be recapped. If it is necessary, however, recapping must be accomplished by means of a mechanical device or a one-handed technique.

— Needles must not be bent, broken, or manipulated by hand.

— Sharp objects must be placed in puncture-resistant containers.

— Appropriate PPE must be used to prevent exposure to blood or body fluids.

— Hands and other skin surfaces that are contaminated with potentially infectious fluids must be immediately and thoroughly washed.

— Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses must be prohibited in work areas where there is a reasonable likelihood of occupational exposure to chemical or biological materials.

— Food and drink must not be kept in refrigerators, freezers, or cabinets or on shelves, countertops, or benchtops where blood or other potentially infectious materials are present.

See also HICPAC (1996) and Garner and Favero (1985).

Rationale: “Standard precautions” represent a philosophy that assumes that all body fluids and items that have contacted body fluids are potentially infectious. If all items are treated as infectious, then employees will be assured of protection, especially when handling items from patients whose infectious status is unknown.

5 Immediate handling of contaminated items at point of use

5.1 General rationale

This section provides guidelines for segregating and handling contaminated items at the point of use. The possibility of items being contaminated with infectious material is greatest at the point of use, where they have been in patient contact. Procedures should be developed, with support from the infection control and hazardous material personnel within the health care facility, to protect the patient, employee, and environment from contamination. The procedures should contain specific directions concerning handwashing practices, techniques to minimize the handling of contaminated items and other hazardous materials, and applicable OSHA regulations. Each health care facility should assess its particular needs.

5.2 Separation of waste and reusable items at point of use

Reusable items should be separated from waste at the point of use. Contaminated disposable items should be discarded into an appropriate container; puncture-resistant containers must be used for sharps. All items contaminated with blood, body fluids, and tissue must be placed in a leakproof container before transport. Contaminated reusable items should be contained in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items. When the outside of a transport container/cart is visibly soiled, it should be decontaminated prior to transport with an EPA-registered, intermediate-level disinfectant (see 2.13 and annex C). Containment should comply with the health care facility’s established infection control and hazardous waste management procedures (see also 6.2). Procedures that reduce the potential for contamination of personnel, their clothing, and the environment should be developed and followed. Depending on the nature and amount of waste to be separated and the possibility of contamination, it might be necessary for personnel to wear appropriate PPE such as gloves, protective eyewear, a surgical face mask, and a protective backless gown, jumpsuit, or surgical gown (see 4.4). Other measures also may be adopted for infection control purposes or as part of hazardous waste management. Contaminated items should be handled as little as possible.

Rationale: Separation of soiled reusable items and waste at the point of use will minimize handling and therefore minimize the possibility of subsequent exposure to potentially disease-producing organisms. Separation is best done at the point of use by persons aware of the potential for injury from sharps and the potential infection hazards of the contaminated items. Contaminated reusable items, contaminated disposable items and waste, and tissue specimens are placed into specifically labeled containers to prevent exposure of personnel to potentially infectious materials and prevent contamination of the environment. The specified characteristics of containers for sharps and other contaminated items are based on OSHA regulations (29 CFR 1910.1030).

5.3 Care and handling of contaminated reusable items at point of use

Contaminated reusable items should be handled as little as possible at the point of use. Soiled items should be immediately contained and transported to a designated area, where cleaning procedures can be accomplished away from patient care. In many health care facilities, however, immediate containment, transportation, and cleaning might not be feasible, so gross soil should be removed at the point of use. When handling contaminated items, personnel should wear appropriate PPE (see 4.4) and use work-practice controls and engineering controls, as appropriate, to minimize the risk of injury. Soil should be removed by a method that does not promote cross-contamination; for example, personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment. A disposable sponge moistened with water (not saline) should be used to wipe gross soil from instruments. Gauze sponges and similar items used in the cleaning process are contaminated and should be handled, contained, and discarded according to hospital policy for infectious wastes.

Rationale: Contaminated items must always be handled so as to minimize potential exposure of workers to disease-producing organisms and contamination of the environment. Immediate containment and transport to a designated area minimizes the risk of employee contact with contaminants and allows the cleaning process to be performed in a controlled environment by personnel who are protected with PPE.

Gross soil is removed as soon as possible in order to (a) reduce the number of microorganisms on the item; (b) reduce the nutrient material that might support microbial growth; (c) reduce the potential for environmental contamination by aerosolization or spillage; and (d) minimize damage to devices from such substances as blood, saline, iodine, and radiological dyes or from the subsequent vigorous cleaning processes needed to remove encrusted material. Because it cannot be known for certain which patients harbor bloodborne viruses or disease-producing bacteria, the use of PPE is necessary for the protection of the health care worker.

6 Transportation

6.1 General rationale

This section provides guidelines for the transport of contaminated items from the point of use to the decontamination area. Procedures for safely transporting contaminated items are important, because many people—workers, patients, and visitors—can be exposed to potentially disease-producing microorganisms during transport. In addition, the general hospital environment is not controlled and persons encountered during transport will not be wearing PPE.

6.2 Containment

Contaminated items should be contained during transport from the point of use to the decontamination area. Containment may be accomplished by any means that adequately prevents personnel contact with the contaminated items during transfer. Containers, devices, and/or carts must be marked with a biohazard label or other means of identifying contaminated contents; a red bag or container may also be used to denote that the contents are hazardous. The type of container that should be used depends on the items being transported. Bins with lids, enclosed or covered carts, closed sterilization container systems, and impermeable bags are among the types of containers that may be used alone or in combination to transport contaminated items. Puncture-resistant containers must be used for devices with edges or points capable of penetrating container or skin. See also 5.2.

Immediately after use, items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use. Transporting contaminated items in liquid should be avoided; if items are soaked in water or an enzymatic solution at the point of use, the liquid should be discarded by properly attired personnel before transport.

Reusable collection containers for holding contaminated items should be made of material that can be effectively decontaminated; containers designated for single use should be made of material that can be incinerated or otherwise disposed of following use. Environmental issues and hazardous waste policies should be considered before single-use containers are selected as a containment method.

Rationale: Contaminated items harbor microorganisms that could cause infection in susceptible hosts. Containment minimizes the possibility of airborne or contact spread of microorganisms. Keeping items moist prevents soil from drying on device surfaces and facilitates the decontamination process. In general, contaminated items should not be

transported in liquid because of the risk of spills, promotion of biofilm formation, and possibility of employee injury from lifting a heavy container.

6.3 Transportation equipment

The transport system should be designed to prevent items from falling over or falling off during transport. Carts should be large enough to maintain the security and package integrity of the items being transported. A covered or closed transport cart is desirable. Carts, reusable covers, and containers/bins should be decontaminated after each use.

Rationale: Transportation equipment of appropriate design will help prevent damage to reusable items and avoid contamination of the environment. Decontamination of transportation equipment after each use helps prevent cross-contamination of items transported at a later time.

6.4 Transportation scheduling and routes

The pickup and transport of soiled items from each area should be scheduled so that items are transported and cleaned as soon after use as possible. Transport routes should be designed to facilitate efficient pickup and delivery to the decontamination area and, whenever possible, avoid areas of high traffic.

Rationale: The amount of time between use and decontamination should be minimized because the soil on items provides an excellent medium for microbial reproduction. Also, cleaning items as soon as possible helps prevent the formation of biofilm and drying of blood, tissue, and mucus on the items, which makes cleaning even more difficult to perform.

6.5 Transportation between buildings

The transportation system should be designed to minimize the risk of personnel exposure to bloodborne and other disease-producing organisms and possibility of damage to the instruments/items being transported. Consideration should be given to the containment/packaging of the items, loading procedures, temperature control in transportation vehicles, and other relevant factors. Contaminated items should not be transported in the same vehicle as clean/sterile items. Because contamination of the vehicle might have occurred, transportation vehicles should be decontaminated before they are used to transport sterile items. Transportation personnel should receive training in basic infection control principles as they relate to their responsibilities. Personal protective equipment and a biohazardous spill kit should be available in transportation vehicles.

Rationale: Additional factors such as temperature changes that may enhance microbial growth should be considered when contaminated items are transported outside the controlled environment of the health care facility. Clean/sterile items and contaminated items should not be transported in the same vehicle because of the risk of cross-contamination. Training is needed to help reduce the risk that transportation personnel will be exposed to bloodborne and other pathogens. Personal protective equipment should be available for use in the event of spills of contaminated items/fluids.

6.6 Off-site transportation

The procedures for packaging and transporting contaminated items off-site for processing must comply with applicable U.S. Department of Transportation (DOT) and state regulations. See also annex E.

Rationale: Certain contaminated, “nonwaste” products are considered to be “infectious substances” under DOT regulations. The DOT defines an infectious substance as a product contaminated with “viable microorganisms . . . which cause or may cause disease in humans . . .” (49 CFR 173.134 (a)(1)). Such products qualify as Class 6, Division 6.2, hazardous materials and thus fall under DOT’s regulations for “Infectious Substances (Etiologic Agents).” Certain states also have regulations that can affect the transport of contaminated items.

7 Decontamination processes

7.1 General rationale

To assist health care personnel in the development of appropriate decontamination processes and procedures for the various types of medical devices, this section provides guidelines for the selection and use of available cleaning and microbicidal processes.

To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process (e.g., bedpans), while others must be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments).

The level of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The type of cleaning and/or microbicidal process appropriate for a particular device depends on

a) the device manufacturer's written instructions;

b) the necessary level of microbial kill (for example, a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or body fluids than for items that have only been in contact with unbroken skin);

c) the design of the device (for example, items that have been contaminated with blood or body fluids and have sharp points or edges capable of puncturing or abrading the skin should be subjected to a decontamination process that includes high-level disinfection or sterilization);

d) other characteristics of the device (for example, whether the materials from which the device is fabricated can tolerate high temperatures);

NOTE—Health care personnel, including representatives of central service and infection control, should make a concerted effort to purchase only those devices that can be decontaminated appropriately by a method available in the health care facility. Device manufacturers have the responsibility to provide complete and comprehensive written instructions for the decontamination of their products, and a summary and interpretation of test results verifying that their products can be safely and effectively decontaminated. See AAMI TIR12 and FDA (1996).

e) whether the device was exposed to prions such as the prion that causes Creutzfeld-Jakob disease (CJD) and thus will require specialized processing steps.

NOTE—For information regarding the decontamination of devices exposed to prions, see AORN (2002a), Favero & Bond (2001), Rutala & Weber (2001), and the recommendations of CDC (<http://www.cdc.org>), the American Society for Health Care Central Service Personnel (<http://www.ashcsp.org>), and the International Association of Healthcare Central Service Materiel Management (<http://www.iahcsmm.com>).

7.2 Presoaking

Presoaking with a specialized product (for example, an enzymatic solution) is generally recommended. When presoaking instruments, personnel should refer to the solution manufacturer's instructions for the correct dilution, temperature, and soak time. Instruments should be thoroughly rinsed after presoaking.

Rationale: Presoaking instruments loosens the soil, thus making the cleaning step easier. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution.

7.3 Sorting and disassembly

Upon arrival in the decontamination area, contaminated items should be removed from their transport containers, sorted, and prepared for cleaning. Surgical instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) should be disassembled to expose all surfaces to the cleaning process. Device manufacturers' instructions for disassembly and reassembly of all items processed should be included in the procedure manual for the decontamination area. Care should be taken to ensure that all small parts (e.g., screws, nuts, and washers) are contained to prevent loss. Noninterchangeable components of assemblies, such as parts of a metal stopcock, should be kept together to ensure correct reassembly. Procedures should be developed to ensure that personnel do not reach by hand into the container to retrieve reusable sharps that may be hazardous and contaminated with blood or other potentially infectious material.

Rationale: Hidden surfaces and crevices can prevent thorough cleaning. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. The recommended procedures for disassembly and reassembly are intended to help ensure that reassembly can be accomplished without loss of time or damage to important equipment. The recommendation concerning reusable sharps is based on OSHA regulations (29 CFR 1910.1030).

7.4 Cleaning

7.4.1 General

For all reusable medical devices, the first and most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms. Because the cleaning process is not quantifiable (i.e., the number of microorganisms removed or killed each time is not consistent), a subsequent microbicidal process might be necessary to ensure that an item is safe for handling.

Effective cleaning is a multistep process that relies on several interdependent factors: the quality of the water; the quality and type of detergent; an acceptable washing method; proper rinsing and drying; correct preparation of items

to be processed by cleaning equipment; the time and temperature parameters and load capacity of the equipment; and operator performance.

Rationale: The purpose of cleaning and rinsing is to remove all visible debris from an item and reduce the number of particulates, microorganisms, and potential pyrogens. The accepted standard for the degree of cleanliness is "visibly clean." Thorough cleaning and rinsing are vital to the effectiveness of subsequent microbicidal processes used for decontamination, disinfection, and/or sterilization. The amount of residue that remains may vary depending on the conditions of use of the cleaning agents, specific component materials of the reprocessed devices, and methods used to reduce residuals prior to reuse. Any organic material and/or residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants and protect microorganisms from destruction. In addition, debris may become dislodged and cause potential health risks such as a foreign-body reaction or breeding place for an infection. The water used to perform the final rinse of the device should be endotoxin-free in order for the device to be pyrogen-free. Low bioburden should result from adequate cleaning and rinsing, and is essential to the effectiveness of terminal sterilization and the protection of patients from pyrogens.

7.4.2 Cleaning agents

Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to clean. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning. It must be rehydrated and then washed away. Blood adheres to surfaces through mechanical and chemical means. Fibrin filaments in coagulated blood pack themselves into microscopic irregularities in the surface of instruments and have to be mechanically scrubbed away or chemically attacked in order for the filaments to be removed. High pH detergents, enzymatic solutions, mechanical scrubbing, and high-pressure water spray perform this function. Neutral pH detergents do not dissolve fibrin filaments but work well in combination with enzymatic solutions.

Proteinaceous blood components such as albumin are water-soluble and simple to wash away unless they have been denatured (made insoluble) through thermal or chemical means. Hot water, concentrated alcohol, and glutaraldehyde can denature blood proteins, making cleaning much more difficult. An initial cool-water rinse can wash away blood's water-soluble proteins and prevent denaturing. Soaking in concentrated alcohol should be avoided. Solutions that contain alcohol should be diluted according to the manufacturer's specifications before contact with blood-soiled instruments. Heat from excessively long exposure to ultrasonic cleaning also can denature blood. Ultrasonic cleaning procedures should not allow blood to be exposed to temperatures higher than 130 ^{o}F.

The primary agent that affects cleaning is the detergent solution or combination of detergent and enzymatic solution. The delivery system used to bring the detergent solution to the instruments should do so effectively, but the actual cleaning is done by the detergent solution.

The device manufacturer's instructions should be consulted to determine the appropriate type of cleaning agent. The cleaning agent manufacturer's instructions for use should be followed.

Rationale: Certain detergents can damage metal or other device materials. It is the responsibility of device manufacturers to advise the user about cleaning agents that will and will not harm their products.

7.4.3 Methods of cleaning

7.4.3.1 Selection of an appropriate method

The appropriate cleaning method for a particular medical device depends on the device's characteristics. Cleaning may be accomplished manually, mechanically, or by a combination of both methods. The cleaning method(s) selected should be effective, not affect the functionality of the device, and be safe for the employee performing the task. It is the responsibility of the reusable device manufacturer to provide reprocessing instructions in the labeling of the device (e.g., in the instruction/user manual). These instructions may recommend use of a particular type of cleaning equipment and/or particular cleaning agent. Before health care personnel elect to use alternative equipment and/or cleaning agents, the manufacturer of the cleaning equipment/product and device manufacturer should be consulted.

Rationale: Medical devices vary in size, complexity, fragility, sensitivity to cleaning agents, immersibility, and other properties that affect the choice of cleaning method. See also AAMI TIR12.

7.4.3.2 Manual cleaning

Any device should be able to be cleaned manually. Manual cleaning often is recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. Immersible devices should be cleaned under the water level to minimize aerosolization; devices that cannot be immersed should be cleaned in a manner that will not produce aerosols, rinsed, and dried according to the device manufacturer's instructions. Lukewarm water/detergent solutions (at temperatures below 43 °C (110 °F)) will prevent coagulation

and thus assist in the removal of protein substances. Water hardness, temperature, and type of soil affect the effectiveness of detergents; the detergent manufacturer's instructions should be consulted. Abrasive cleaning compounds and implements damage devices and should not be used without specific instructions from the device manufacturer. Devices should be thoroughly rinsed to remove debris and detergent residues. Brushes and other cleaning implements should be disinfected or sterilized daily.

Rationale: Microorganisms, patient tissue, blood, and lubricants on brushes and other cleaning implements could be transmitted from one device to the next during the use of cleaning implements. In addition, accumulated microorganisms, patient blood, and patient tissue on cleaning implements could pose potential health risks to personnel.

7.4.3.3 Mechanical cleaning

Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process. Some types of equipment incorporate thermal disinfection processes and/or chemical disinfectant rinses capable of destroying various numbers and types of microorganisms. Mechanical cleaning equipment includes utensil washers and cart washers, washer-sanitizers, pasteurization equipment, washer-disinfectors, washer-decontaminators, and washer-sterilizers (see also 7.5.2.3). Some types of mechanical cleaning equipment are designed to clean and/or disinfect specific kinds of medical devices such as endoscopes.

Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods. Ultrasonic cleaning should be used only after gross soil has been removed from items. The water or cleaning solution should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited by soil and the risk of cross-contamination is minimized. In any case, ultrasonic cleaning should be followed by thorough rinsing to remove dislodged particles. Ultrasonic cleaners may require degassing when they are filled with water; the ultrasonic cleaner manufacturer should be consulted for instructions. The medical device manufacturer should be consulted to ensure that ultrasonic cleaning will not damage the device. Not all metals can be mixed in the ultrasonic process, and the device manufacturer should specify any restrictions.

For any mechanical cleaning unit, regular preventive maintenance should be performed in accordance with the manufacturer's instructions.

Rationale: The ability to clean medical devices mechanically and fine-clean by the ultrasonic process is of great value, considering the complexity of many devices and heavy workload of the average sterile processing department. However, the variety of equipment available and intricacy of many medical devices make it essential that manufacturers be consulted and their instructions followed for maximum effectiveness and to avoid expensive and unnecessary damage.

7.4.4 Verification of the cleaning process

Upon completion of the cleaning process, each item should be carefully visually inspected to detect any visible soil. While validation of the cleaning process is not realistic in health care facilities today, verification is possible. Device manufacturers should provide any test procedures that can be easily replicated and help users recognize whether cleaning was effective for all device surfaces. Such tests are particularly important for devices with components that cannot be readily inspected for cleanliness (e.g., spring hinges, lumens, porous materials, crevices). For example, a 2 % hydrogen peroxide solution has been used to verify the removal of protein from the lumens of instruments such as needles and tracheostomy tubes; the solution bubbles if it comes into contact with blood or protein surfaces. See also AAMI TIR12.

Rationale: There is an increasing awareness in sterile processing of the need to control and standardize the steps taken to ensure a sterile device for patient use. With the understanding that disinfection and sterilization cannot be ensured unless the cleaning process is successful, it is incumbent upon professionals in the field to seek out whatever means are available and practical to verify this function. A quality system would call for the decontamination processing parameters to be monitored and documented, whether the process was accomplished by hand or mechanically.

7.5 Microbicidal processes

7.5.1 General

Cleaning alone might not adequately decontaminate items that by their design, the nature of their contamination, and/or their intended use present a high risk of disease transmission to workers or patients. Such items include devices that have been in contact with blood or other body fluids (e.g., surgical instruments) and devices that can cause cuts or puncture wounds (e.g., reusable needles and sharp-edged devices). After such items have been cleaned, they should be subjected to a microbicidal process. Microbicidal processes include disinfection and sterilization by thermal or chemical means.

Rationale: As compared to cleaning alone, microbicidal processes provide a higher assurance of microbial kill and thus an increased margin of safety for personnel who will be handling items that pose a high risk of disease transmission. It is not possible to eliminate all risk. A realistic goal is to develop a process that provides a high level of confidence that the decontamination procedures produce a reasonable level of safety without compromising processing efficiency.

7.5.2 Disinfection processes

7.5.2.1 Levels of effectiveness

Disinfection processes offer varying degrees of microbial kill or reduction. They are commonly divided into three levels of effectiveness (Favero and Bond, 2001):

a) Low-level disinfection reduces the overall number of vegetative microorganisms, medium or lipid viruses, and some fungi, but it cannot be relied upon to destroy tubercle bacilli, bacterial spores, or small or nonlipid viruses.

b) Intermediate-level disinfection will kill vegetative microorganisms, tubercle bacilli, most viruses, and fungi (including asexual spores but not necessarily dried chlamydospores or sexual spores), but it is not necessarily capable of killing bacterial spores.

c) High-level disinfection will kill most forms of microbial life, including vegetative microorganisms, tubercle bacilli, most viruses, and, with extended exposure times, high numbers of bacterial spores.

Depending on such variables as concentration, temperature, and contact time, the same physical process or chemical agent can be used to achieve more than one level of effectiveness. The labeling, manufacturer's claims, and supporting data always should be reviewed to ensure that the correct process or product has been selected.

7.5.2.2 Chemical disinfection

Chemical disinfection may be performed by manually soaking an item in a basin of liquid chemical germicide solution, or by automated equipment such as washer-disinfectors, which provide a cycle of cleaning, rinsing, disinfection, and drying. Commonly used liquid chemical disinfectants contain agents such as glutaraldehyde, chlorine compounds, phenols, quaternary ammonium compounds, orthophalaldehyde, and hydrogen peroxide, singly or in combination.

Liquid chemical germicides that are intended to process reusable critical and semicritical medical devices are regulated only by the FDA and are subject to FDA requirements in the regulation that was final on June 8, 2000; they are exempt from U.S. Environmental Protection Agency (EPA) regulations promulgated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The FDA Special Control Guidance, *Content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants* (FDA, 2000a) describes the FDA regulation and requirements in detail. Liquid chemical germicides that are used for nonmedical uses such as general-purpose disinfectants are regulated by EPA as part of FIFRA. Occupational exposure to some chemical disinfectants is regulated by OSHA.

Under FDA regulation, the labeling for liquid chemical sterilants/high-level disinfectants must provide information relating to safe and effective use. The FDA has described guidance for basic labeling in FDA (1996) and FDA (2000a). The labeling for liquid chemical germicides should identify the active ingredients and their concentrations. It should provide information on measuring the minimum recommended concentration (MRC) or minimum effective concentration (MEC) prior to use, the required contact time, use temperature, reuse pattern, material/device compatibility, necessary PPE, stability, and shelf life. It also should provide any additional information needed by the user for the safe and effective use of the product. The labeling includes a package insert containing all of the above information and any supplemental information for the user. The FDA labeling requirements for these products rely on the broader disinfection terms defined by Spaulding (1972) to indicate product effectiveness, so the terms used in EPA-mandated labeling ("virucidal," "fungicidal," "bactericidal," and "tuberculocidal") have been phased out. Additionally, under FDA labeling policy, reference to specific diseases such as AIDS is not permitted unless effectiveness has been shown in clinical trials. For some products, OSHA requires the manufacturer to supply a material safety data sheet (MSDS).

Knowing the spectrum or range of antimicrobial activity of any particular disinfectant formulation is critical in choosing a disinfectant appropriate to the level of decontamination required for the devices being processed. The chemical agents in disinfectants have been classified according to their ability to kill or inactivate bacterial spores, vegetative bacteria, viruses, and fungi (see annex C).

For automated chemical disinfection systems, the effectiveness of the process relies heavily on coordinating the recommendations of the device manufacturer, disinfection equipment manufacturer, and manufacturer of the

disinfectant solution. For any automated chemical disinfection unit, regular preventive maintenance should be performed in accordance with the equipment manufacturer's instructions.

It is essential to use chemical disinfectants with care to avoid potential health hazards. It is important to follow the disinfectant manufacturer's instructions for rinsing.

Annex C provides guidelines on the selection and use of chemical disinfectants.

7.5.2.3 Thermal (hot water) disinfection

Thermal disinfection is commonly accomplished with automated equipment such as washer-sanitizers, pasteurization equipment, washer-decontaminators, and washer-disinfectors. The level of disinfection achieved depends on the water temperature and contact time. Contact time is inversely related to temperature (i.e., for equivalent microbial kill, substantially longer exposure times might be required when the temperature is reduced). Recommended water temperatures and contact times vary from manufacturer to manufacturer and among the major categories of equipment. In general, however, the following categories of equipment are associated with increasing levels of disinfection, with washer-sanitizers providing the lowest level and washer-disinfectors the highest.

a) Washer-sanitizers, washer-decontaminators, utensil washers, and cart washers reduce microbial contamination by means of cleaning agents, hot water, rinsing, and drying. Some types of equipment include chemical disinfectant rinses. No specific claims of microbicidal efficacy are generally made for this type of equipment, and the actual results may range from low-level disinfection (sanitization) to intermediate-level disinfection.

b) Pasteurization equipment provides cleaning and high-level disinfection at water temperatures of 65 °C to 77 °C (150 °F to 170 °F) for a contact time of at least 30 min.

c) Washer-disinfectors provide a cycle of cleaning, rinsing, disinfection, and drying at temperatures that are usually higher than those of washer-sanitizers. Some types of equipment can be programmed to vary temperature and/or contact time, and some incorporate chemical disinfectant rinses. Washer-disinfectors can provide high-level disinfection, depending on the moist heat exposure time and temperature. Washer-disinfectors that use disinfecting chemicals also can provide high-level disinfection, depending on the exposure time and disinfecting agent used.

For any thermal disinfection equipment, regular preventive maintenance should be performed in accordance with the manufacturer's instructions.

Further information about thermal disinfection is provided in annex D.

Rationale: The CDC guidelines prescribe the proper level of final processing between patient uses for critical, semicritical, and noncritical items (Garner and Favero, 1985). Thermal disinfection is usually an interim step in the processing of medical devices; that is, it is intended to render the items safe to handle by personnel not wearing protective attire, not to process them fully for reuse in patient care. Even if steam sterilization is used as a decontamination step, as in a washer-sterilizer, the items are not considered patient-ready (see 7.5.3.1). Critical items always would be subjected to a sterilization process after decontamination is complete, and semicritical items usually would be subjected to either sterilization or high-level chemical disinfection. An exception is made for some semicritical items undergoing pasteurization. While the characteristics of pasteurization do not support a claim of high-level disinfection according to the CDC guidelines (the ability to kill all microbial life except large populations of bacterial spores), many semicritical items such as respiratory therapy and anesthesia devices are ready for patient use after cleaning and pasteurization. High numbers of bacterial spores are not generally found on this equipment after use, cleaning prior to pasteurization reduces the bioload substantially, and the low numbers of spores that might be present on a properly processed device would not present an infective dose when contacting intact mucous membranes. The FDA has cleared one or more processes using pasteurization time/temperature relationships as high-level disinfection. For noncritical items, processing through a washer-decontaminator or washer-disinfector is more than adequate sanitization, even if heavily contaminated with blood or other potentially infectious materials (OPIM).

7.5.3 Sterilization processes

7.5.3.1 General

The use of a sterilization process as the final step in decontamination offers the highest level of microbial kill. After decontamination, all items should be inspected for cleanliness and functionality. If the items are intended for noncritical use (e.g., bedpans, other patient utensils), no further processing is necessary.

When mechanical cleaning and a sterilization process are combined and performed in a single machine, the items processed by this means are generally not suitable for immediate use in a sterile procedure. For example, an

instrument set processed through a washer-sterilizer should not be considered safe and sterile for patient use, although it is safe for personnel to handle.

A process using a machine specifically designed to clean and sterilize or high-level disinfect a specific type of device such as a flexible endoscope or dental handpiece can result in an item that is safe to use in patient care where contact with compromised tissue is anticipated. Manufacturers of equipment labeled as combining cleaning and sterilization/high-level disinfection should present scientific evidence that the equipment will perform as intended under usual conditions of use in health care facilities and the processed items can be confirmed by quality assurance as patient-ready.

Some devices cannot tolerate mechanical washing and/or thermal decontamination. Such devices are first thoroughly cleaned, rinsed, inspected, assembled, and (if applicable) packaged by personnel wearing appropriate PPE and then processed through a chemical sterilization process such as ethylene oxide (EO), peracetic acid, hydrogen peroxide alone or in combination with plasma generation, hydrogen peroxide/peracetic acid combinations with plasma generation, or formaldehyde/alcohol combinations. In these cases, the sterilization process is both the final step in decontamination and the preparation for patient use.

Rationale: If a device has not been thoroughly cleaned and rinsed first, dead organisms in soil or organic debris can cause pyrogenic or foreign-body reactions if the sterilized item is used in an invasive procedure. Functionality of the device also could be compromised; for example, the box lock of a hemostat might not close because of residual soil, or the lumen of an item might be occluded. Although a process designed only to decontaminate actually could yield a sterile item, a sufficiently high sterility assurance level cannot be assumed because of the unknown and presumably high bioburden present at the beginning of the cycle. It is difficult to achieve both cleaning and patient-ready sterility or high-level disinfection in a single process. Generally, it only can be done when the process is specifically designed and validated for application to a particular device or family of devices. Combining the biocidal step in decontamination and the terminal sterilization process will yield patient-ready sterile items only if devices are thoroughly cleaned.

7.5.3.2 Chemical sterilization

Liquid chemical sterilants include glutaraldehyde, hydrogen peroxide, hydrogen peroxide/peracetic acid combinations, and peracetic acid. These chemical agents also are used as high-level disinfectants. When these agents are used as sterilants, they must be used at higher concentrations, higher temperatures, and/or significantly longer exposure times than when they are used as high-level disinfectants. Gaseous chemical sterilants include EO, hydrogen peroxide both alone and in combination with plasma generation, hydrogen peroxide/peracetic acid combinations with plasma generation, and formaldehyde/alcohol combinations. As described in 7.5.2.2, the FDA has regulatory authority for liquid chemical sterilants and their labeling. Occupational exposure to sterilants is regulated by OSHA; for some products, OSHA requires the manufacturer to supply an MSDS.

Items should be cleaned thoroughly before they are placed in the sterilant/sterilizer. To document the decontamination or sterilization process, chemical sterilants should be monitored in accordance with the sterilant manufacturer's instructions.

It is essential to use chemical sterilants with care to avoid potential health hazards. To remove toxic residues that might harm workers or patients, it might be necessary to mechanically aerate items that have been processed with a gaseous chemical sterilant (e.g., EO) or to rinse, with sterile water, items that have been processed with a liquid chemical sterilant. The sterilant manufacturer's instructions for use should be followed.

Additional guidelines on the selection and use of chemical sterilants are provided in AAMI TIR7 and Rutala (1996).

7.5.3.3 Thermal sterilization

Saturated steam can be used to decontaminate devices capable of withstanding high temperatures (121 °C to 140 °C (250 °F to 285 °F)) and pressures (16 pounds to 35 pounds per square inch gauge (psig)). The saturated steam process should be monitored routinely with a biological indicator to ensure the efficacy of the cycle (ANSI/AAMI ST46).

Washer-sterilizers provide cleaning and rinsing followed by exposure to saturated steam at temperatures of 121 °C to 140 °C (250 °F to 285 °F). The washer-sterilization process should not be used as terminal sterilization. Devices that must be sterile for patient use should be inspected and prepared for further processing in a steam sterilizer.

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

8.1 General rationale

Medical devices or equipment can be serviced or repaired on-site (i.e., within the health care facility) by hospital employees, manufacturers' representatives, or contract service representatives. There is a potential for service

personnel to be exposed to infectious agents, which can be present either on contaminated devices or in the environment in which the devices are used. Device manufacturers should provide training to their service personnel and instructions to users to help prevent such exposure. Health care institutions should establish policies and procedures to help ensure that service personnel, whether manufacturers' representatives, in-house clinical engineers/biomedical equipment technicians, or third-party service providers, are not exposed to infectious agents.

8.2 Potential for exposure

There are numerous occupational activities in which service or sales personnel can potentially encounter bloodborne pathogens or other infectious agents, such as tuberculosis. These activities include

a) servicing or repairing equipment contaminated with blood or other body fluids or located in isolation rooms;

b) demonstrating equipment during surgical procedures;

c) installing or removing equipment; and

d) inadvertently contacting sharp objects (e.g., needles left in equipment, broken glass, sharp equipment edges).

Some types of equipment present a relatively high potential risk of exposure to service personnel. Equipment in all clinical areas can present risk of exposure, particularly where blood and body fluids flow (e.g., operating rooms, emergency rooms, labor and delivery rooms). Such equipment includes surgical tables (especially the portion beneath the surgical drapes), surgical lights, and warming cabinets. Surfaces remote from the patient can be contaminated by the hands of individuals who have contacted the patient's blood, or the blood can spray or drip onto the equipment. Equipment used in patient transportation, such as stretchers and wheelchairs, can be contaminated in areas not accessible to normal cleaning processes. Care should be taken to prevent exposure when dismantling any equipment used within the health care environment.

Equipment in decontamination areas of central service departments presents relatively high risks to personnel. Cleaning and decontamination equipment found in the decontamination area can be contaminated, and there might be sharps and other potentially hazardous devices in the environment. The nonclean end of sterilizers and sterilizer accessories, such as loading tables, shelving, and transfer carriages, is also of concern.

Clinical laboratories can present significant risk. Any equipment that comes into direct contact with blood, body fluids, body tissues, or OPIM is particularly hazardous.

Since dialyzers come into direct contact with patient blood, much of the equipment in dialysis units should be considered a high-risk source of infection. Respiratory protection for service personnel must be provided by the health care facility in isolation rooms or areas occupied by patients with airborne diseases. Personnel who require access to equipment needing repair in isolation rooms should follow hospital policies and procedures.

8.3 Protective measures for service personnel

8.3.1 General

Service personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, manufacturers and health care institutions should offer hepatitis B vaccinations to their service staff.

8.3.2 Education and training

Education and training programs for service personnel should cover the hazards associated with bloodborne pathogens, requirements of the OSHA standard on occupational exposure to bloodborne pathogens (29 CFR 1910.1030), importance of vaccinations as protective measures, standard precautions, protective work practices, use of PPE, emergency procedures, and procedures to follow if an exposure occurs. See also 4.2.2.

8.3.3 Vaccination

See 4.3.

8.3.4 Personal protective equipment

Personal protective equipment will minimize the possibility of acquiring infectious diseases. The selection and proper use by the worker of the appropriate PPE for the activity being performed are important in protecting service personnel from bloodborne pathogens (see 4.4). Even employees who are adequately protected against hepatitis B by vaccination are at risk of exposure to other infectious diseases.

The health care facility is responsible for providing PPE for all service personnel and ensuring that used, contaminated PPE is decontaminated and/or disposed of properly. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant or liquid-proof clothing, face shields, and surgical face masks. Personal protective equipment should be worn whenever the service person is working on or demonstrating equipment that might be contaminated and whenever the service person is in doubt about the safety of a particular piece of equipment.

8.3.5 Work practices

Before beginning any repair, service, or maintenance, personnel should ascertain whether the user has cleaned and decontaminated the equipment or rendered it safe to handle. Cleaning and decontamination of equipment should be performed by personnel familiar with the appropriate processes. The equipment should be clearly tagged, indicating the extent of decontamination (i.e., only surface decontaminated or internally/externally decontaminated). If no tag is present, it must be assumed that the item has not been decontaminated. See section 7.

Service personnel should not handle potentially infectious materials. The removal, containment, and disposal of infectious or potentially infectious materials is the responsibility of the user or other appropriately designated personnel (e.g., a spill team). Anyone handling infectious materials should be attired in the appropriate PPE (see 4.4), and use the containment and transport methods designated by the hospital.

8.4 Postexposure program

Procedures should be established for handling actual exposure incidents. Such procedures should comply with current CDC recommendations and OSHA regulations.

8.5 Devices that cannot be repaired in-house

See annex E for guidelines on returning devices to the manufacturer.

9 Process performance

9.1 General rationale

Quality assessment is important in minimizing risk to patients, the environment, and health care personnel. Lessening this risk can be achieved only if reusable medical devices are handled, transported, cleaned, and biologically decontaminated under the best possible conditions in a well-designed work area. This section of the recommended practice provides recommendations for process performance measurements for decontamination.

9.2 Quality process

Procedures for decontamination should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in conjunction with the appropriate departments and integrated into the overall quality process in the health care facility. Written policies and procedures should take into account federal, state, and local regulations, CDC recommendations, national voluntary standards and recommended practices, and device/equipment manufacturers' recommendations. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors. Monitoring frequency will vary, depending on the quality improvement goals, hospital policy and procedures for the handling of untoward events, and the type of performance measure.

a) **Design of the decontamination area (section 3).** Performance measures should include, but are not limited to: condition of floors, walls, ceilings, and work stations; ventilation, including air exchanges per hour and air flow pattern; temperature and humidity readings; traffic control; handwashing facilities; and area cleanliness.

b) **Personnel (section 4).** Performance measures should include, but are not limited to: staff education, development, training, and continuing education; verification of competency of personnel; health and personal hygiene; and proper attire, including PPE.

c) **Handling of contaminated items at point of use, containment, and transport (sections 5 and 6).** Performance measures should include, but are not limited to: placement of contaminated items within the containment system; security of containment system; labeling of contaminated items; placement of items on transport carts; security of items on transport carts; and condition of items upon receipt in the decontamination area.

d) **Decontamination processes (section 7).** Performance measures should include, but are not limited to: selection and use of appropriate PPE; sorting and disassembly of instruments; selection and use of cleaning agents; manual cleaning and rinsing; water quality; preparation of items for automatic

cleaning/disinfection; correct loading of items into decontamination equipment and selection of appropriate cycle parameters (time/temperature); accessibility of equipment instrument manuals; verification of installation testing and acceptance; verification of routine inspection and cleaning; verification of routine replacement of parts as recommended by the manufacturer; verification of routine maintenance recommended by the equipment manufacturer (e.g., lubrication, calibration); and inspection of decontaminated items.

e) **Documentation of decontamination processing parameters (section 7).** It is essential that decontamination processing parameters be monitored and documented, whether the process is accomplished by hand or mechanically.

f) **Servicing and repair (section 8).** Performance measures should include, but are not limited to: education and training of service personnel; selection and use of PPE by service personnel; safety of work practices; and adequacy of the postexposure program.

A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to infection control for review.

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

Annex A
(informative)

Examples of workplace design

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

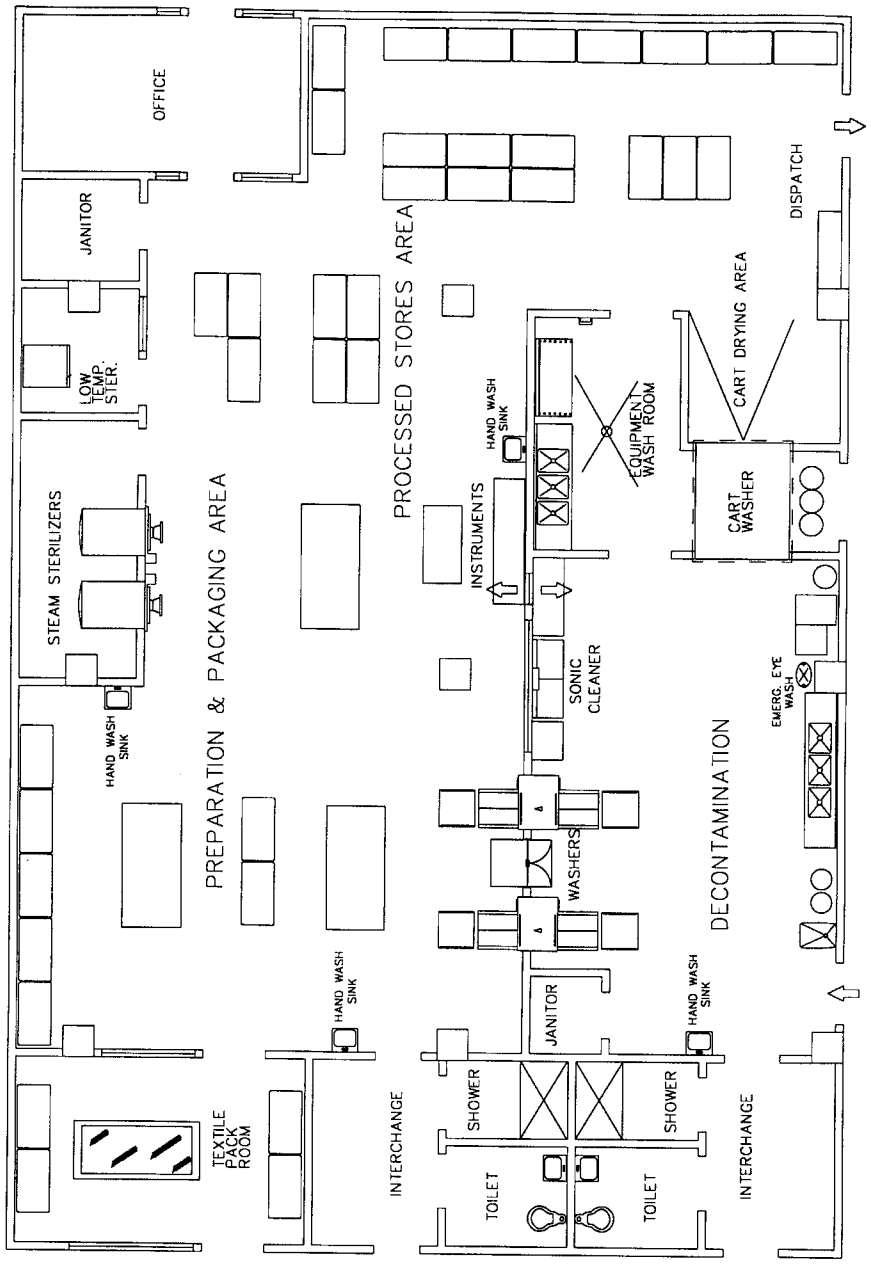

Figure A.1—Example of a work area design and work flow pattern for a sterile processing department in a typical small hospital

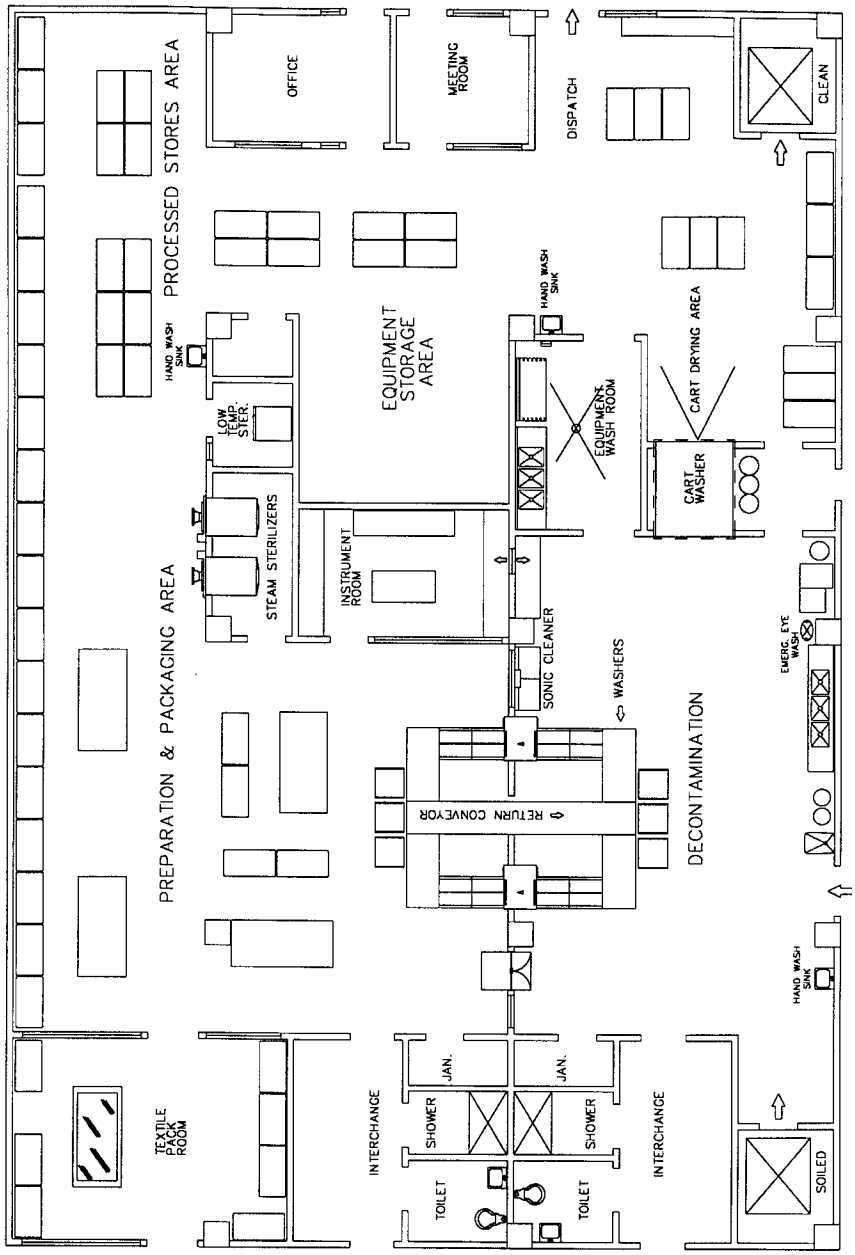

Figure A.2—Example of a work area design and work flow pattern for a sterile processing department in a typical medium-sized hospital

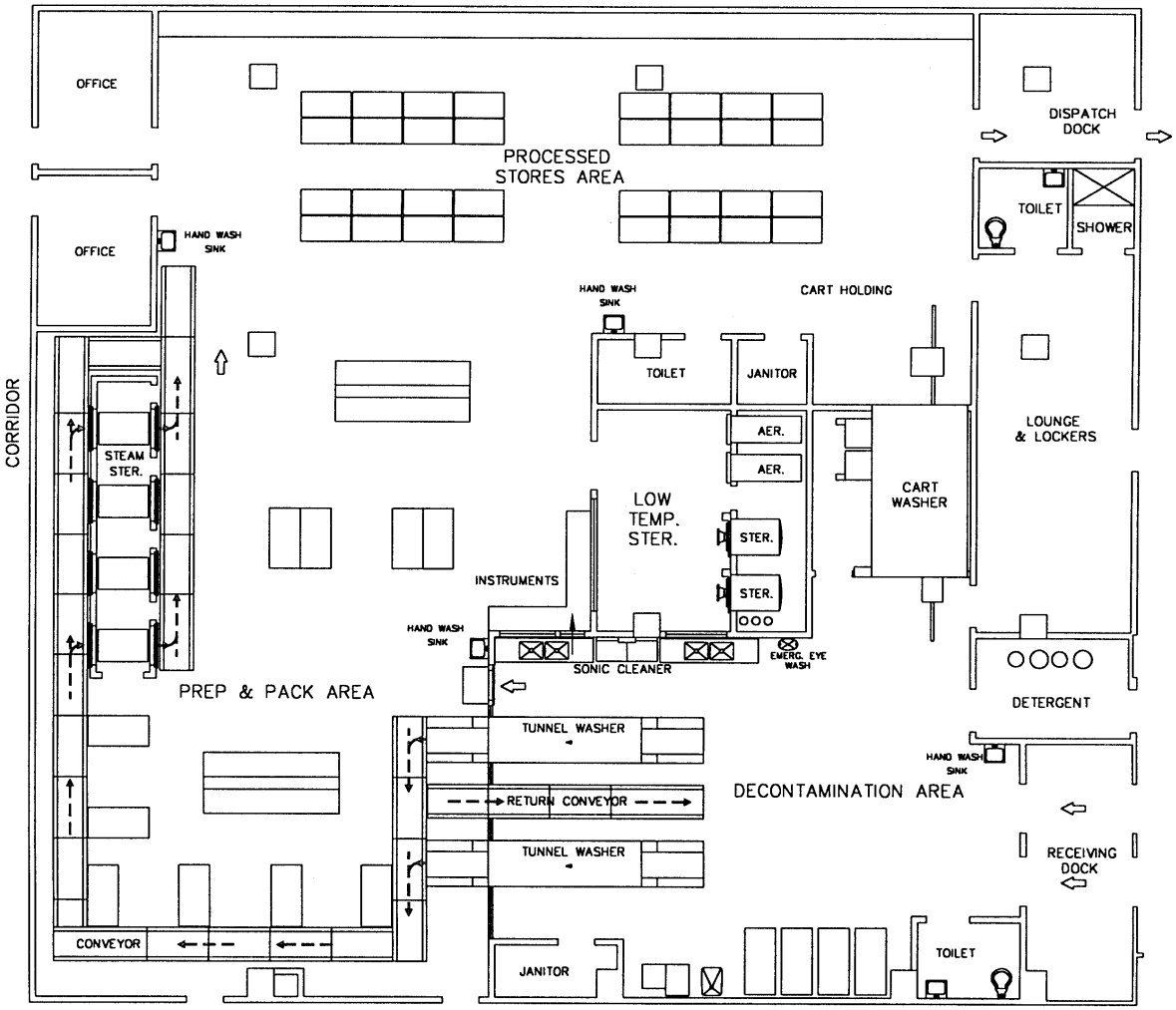

Figure A.3—Example of a work area design and work flow pattern for a sterile processing department in a typical regional processing center

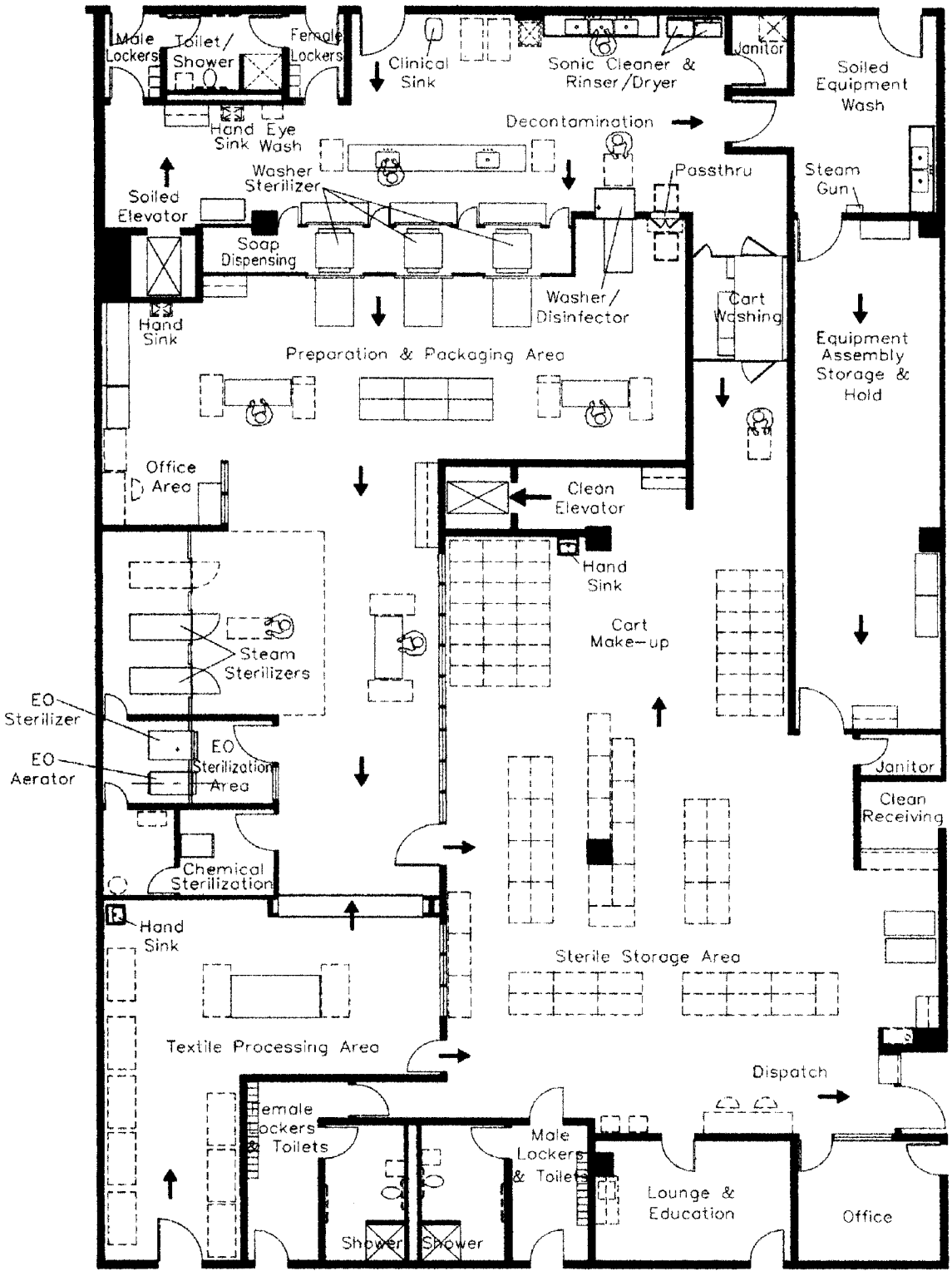

Figure A.4—Example of a work area design and work flow pattern for a sterile processing department

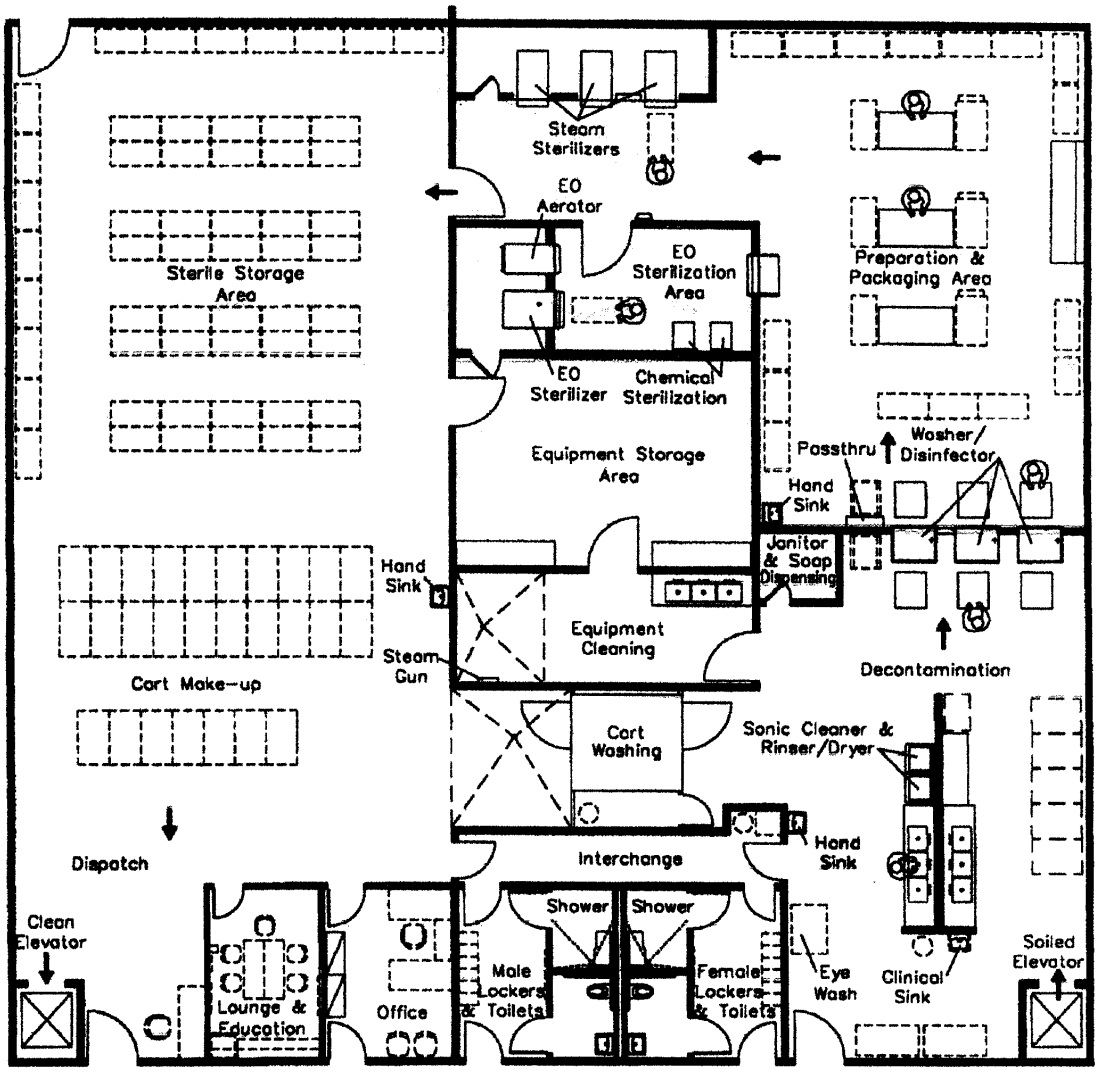

Figure A.5—Example of a work area design and work flow pattern for a sterile processing department

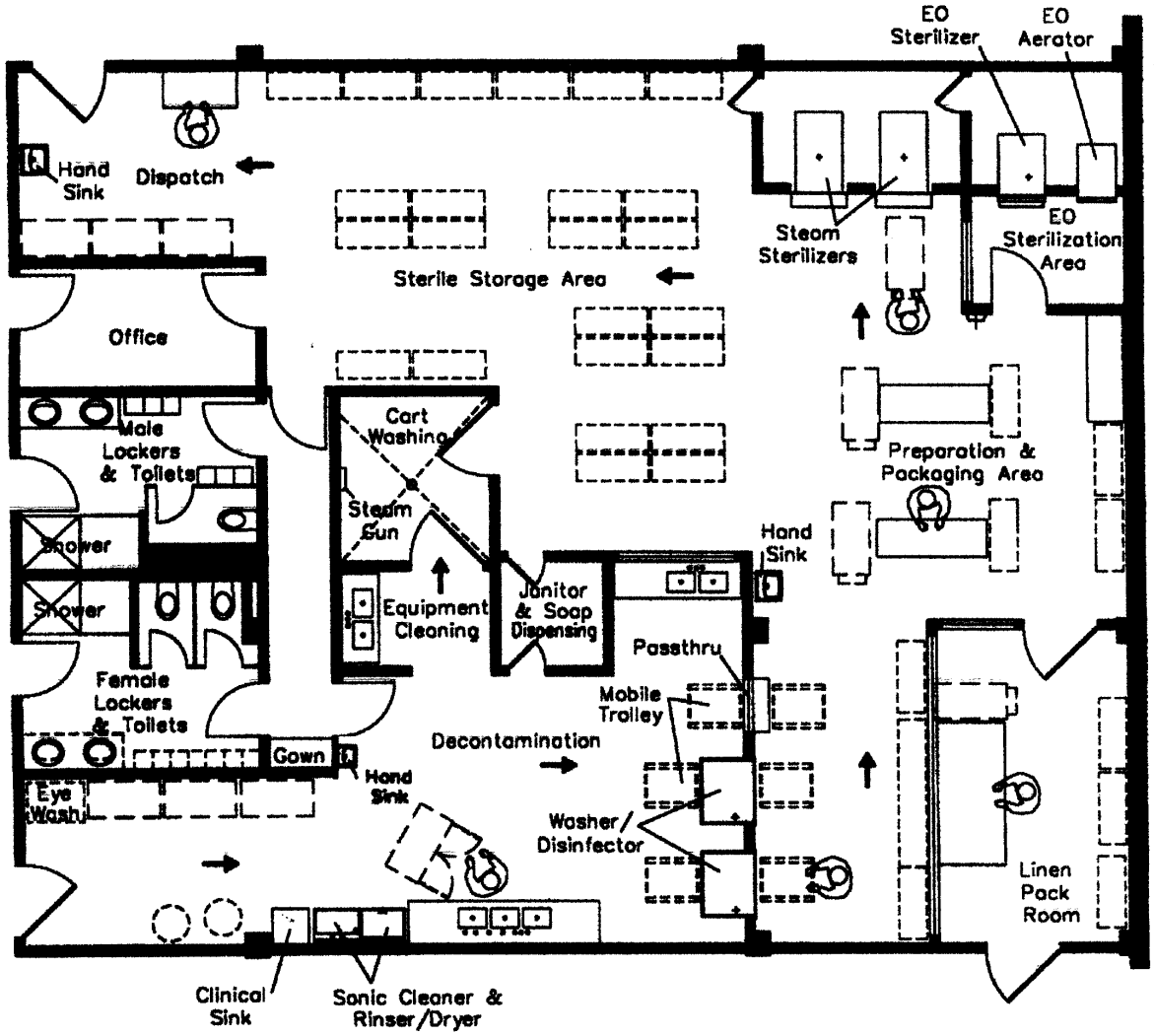

Figure A.6—Example of a work area design and work flow pattern for a sterile processing department

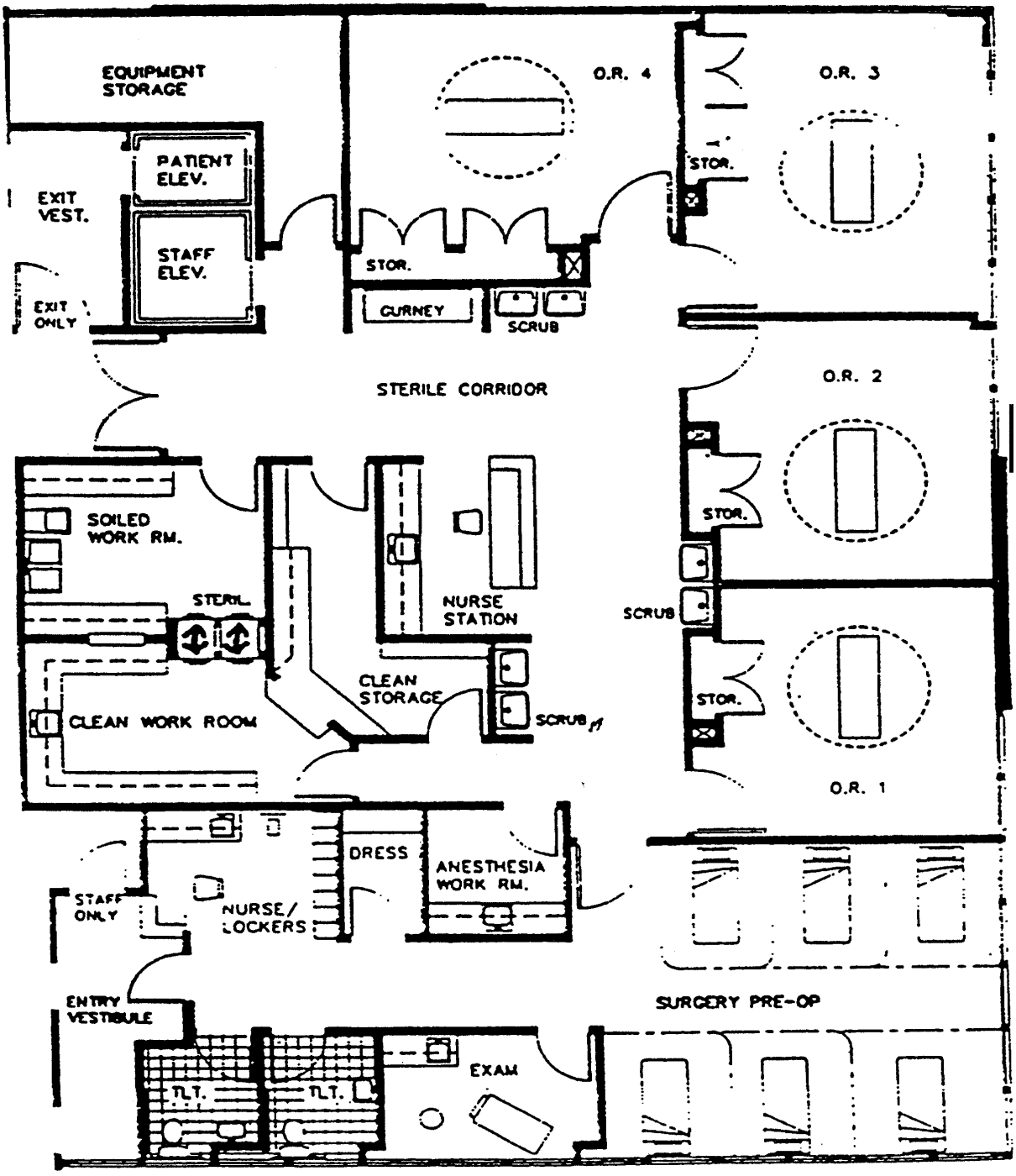

Figure A.7—Example of an ambulatory surgery facility

(Reproduced with permission from the publisher. From Malkin, 1989.)

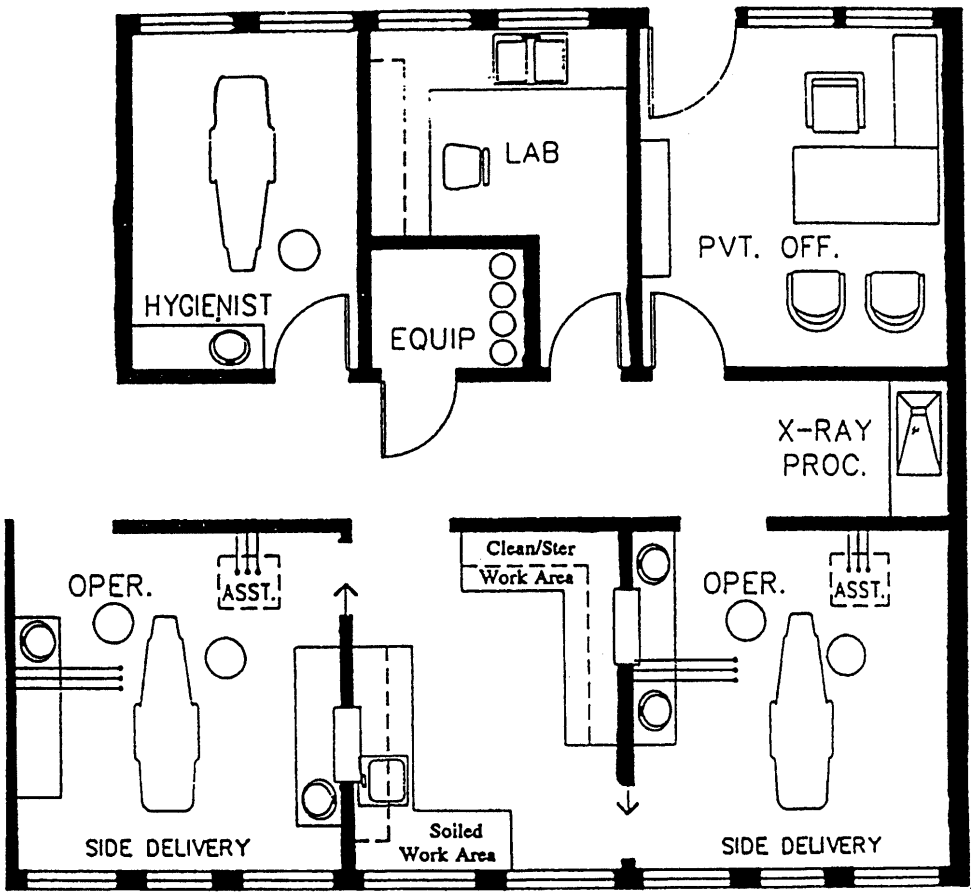

Figure A.8—Example of a dental facility

(Reproduced with permission from the publisher. From Malkin, 1989.)

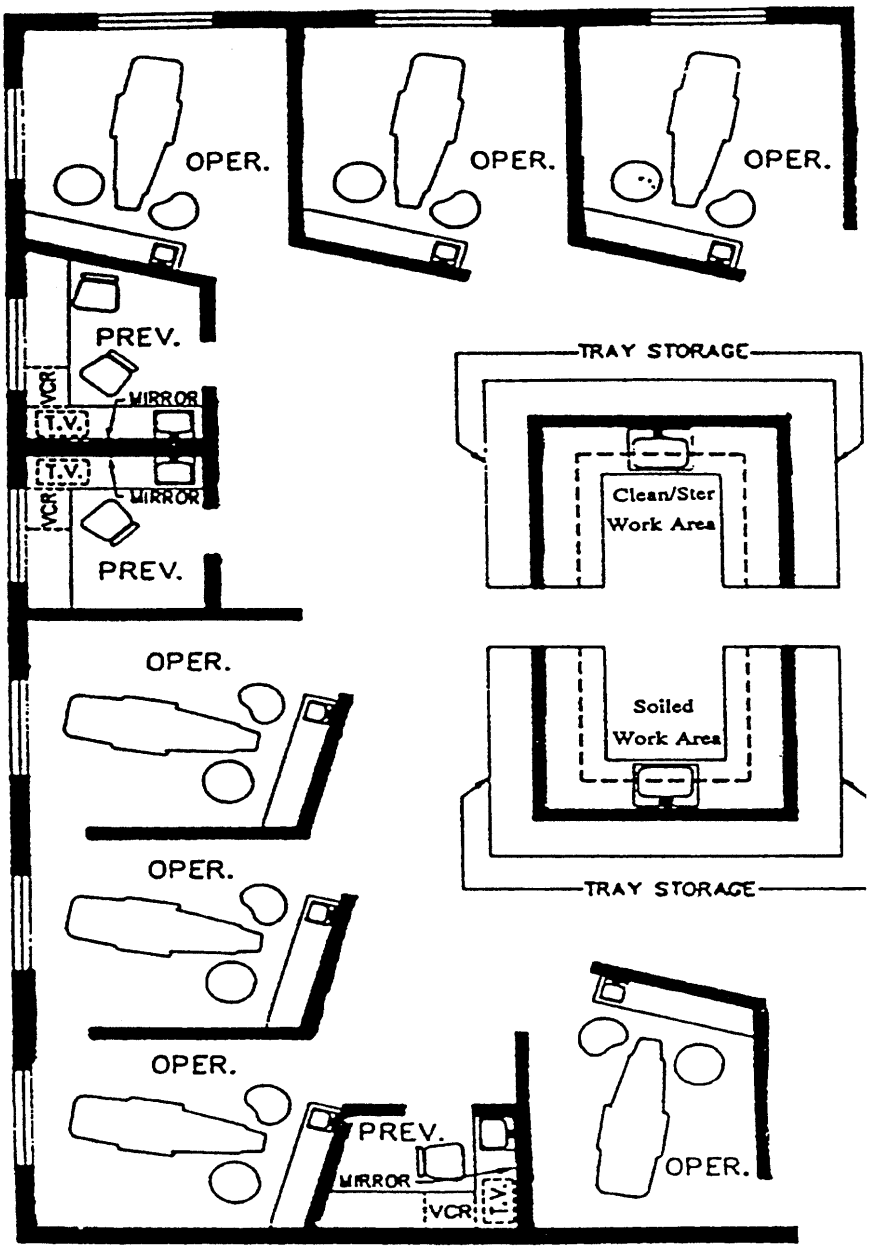

Figure A.9—Example of a dental facility

(Reproduced with permission from the publisher. From Malkin, 1989.)

Annex B
(informative)

Infection transmission

B.1 Introduction

The purpose of the decontamination process in a health care facility is to prevent the transmission of disease. Health care-associated infections can occur because of the presence of infectious agents, multiple modes of transmission, and a population of susceptible individuals. An understanding of the chain of infection enables health care professionals to develop and implement policies and procedures that will reduce the risk of infection transmission.

Health care-associated infections are those that manifest themselves after a patient is admitted to the facility and that were not incubating at the time of admission. Such infections not only involve patients, but also can involve others present in the facility, principally health care workers.

There are six main factors in the chain of infection: the etiologic agent, a reservoir, the portal of exit, mode of transmission, portal of entry, and a susceptible host. (See Figure B.1.) Each of these factors is vitally important, and must be present for an infection to take place.

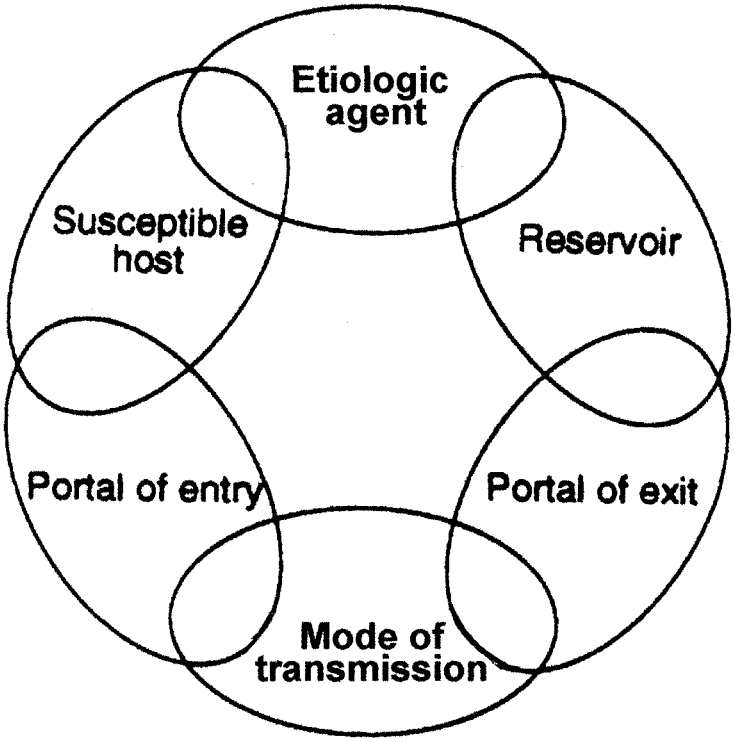

Figure B.1—The chain of infection, components of the infectious disease process

(Adapted with permission from the publisher. From: SOULE BM, ed. *The APIC Curriculum for Infection Control Practice*, Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, Inc., 1983.)

B.2 Chain of infection

B.2.1 Etiologic agent

B.2.1.1 General

The first link in the chain of infection is the etiologic agent itself: any bacterium, virus, fungus, or other microorganism. Most pathogenic microorganisms of concern with respect to patient-care equipment are included in one of the following four classes: (a) spore-forming bacteria such as *Bacillus anthracis*, *Clostridium botulinum*, *Clostridium perfringens*, and *Clostridium tetani*; (b) vegetative bacteria such as *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Mycobacterium tuberculosis*; (c) viruses such as the human immunodeficiency virus (HIV) and the herpes simplex, polio, and hepatitis B viruses; and (d) fungi such as *Candida albicans*, *Coccidioides*, *Aspergillus*, and *Alternaria*.

B.2.1.2 Pathogenicity

Not only must the infectious agent be present, it also must be pathogenic (capable of causing disease). The ability of a microorganism to cause disease depends on its virulence and invasiveness.

Virulence is the degree of pathogenicity of a given microorganism as indicated by morbidity and mortality case rates. Invasiveness is the ability of a microorganism to invade tissues of the body. Organisms that can penetrate the body's intact barriers are generally of more concern than those that cannot. However, some microorganisms need not directly attack intact body tissues in order to cause disease. For example, *Vibrio cholerae* is noninvasive in the gastrointestinal tract but produces toxins that react with the mucosa and cause diarrhea. In contrast, *Shigella* organisms cause disease by actually invading the gastrointestinal submucosa.

B.2.1.3 Dose

A third factor critical to this particular link involves a phenomenon referred to as the "infectious dose." The infectious dose is the minimum number of a given microorganism needed to cause infection. This number varies from organism to organism and from host to host. However, seldom has the transmission of disease resulted from the transfer of a single microorganism. It usually requires thousands to millions of these agents before infection can actually take place. For example, that number for staphylococci has been estimated to be as high as 10^7 (Krizek and Robson, 1975), while the number for hepatitis A may be as low as 10 to 100 virus particles. Some viral diseases can be accompanied by extremely high viral concentrations in body fluids such as blood; consequently, a significant number of microorganisms can be carried in a very minute volume of liquid (Figure B.2). The concept of infectious dose is particularly important to understand when considering the importance and efficacy of good handwashing practices. Although properly performed handwashing does not eliminate all organisms from the skin, it does reduce their numbers to a level far below the infectious dose needed for the transfer of most diseases.

B.2.2 Reservoir

The second major link in the chain of infection involves the presence of a reservoir or source that will allow for microbial survival and, perhaps, even multiplication of a potential pathogen. Common reservoirs include the multitude of supplies and equipment used in patient care. However, the role played by food and drink, linen, and other inanimate objects is of comparatively minor significance when measured against that played by the main reservoir, man himself. Studies have shown that normal human skin harbors approximately 10,000 organisms per square inch, equivalent to nearly 20 million microorganisms over the surface of the entire body. The oral cavity is thought to harbor an additional 100 million organisms and the gastrointestinal tract to contain another 100 million in each gram of stool. Thus, on and within the human body, well over a trillion microorganisms can be found, and therein lies one of the main reasons for the use of gloves any time that contact with body fluids is anticipated. It is a well-documented fact that most health care-associated infections are indeed caused by the patient's own microbial flora. This is not to imply that such infections are nonpreventable, simply that they are usually the result of prior microbial colonization of the patient.

B.2.3 Portal of exit

The third link requires the presence of a source from which the pathogen can emerge: a portal of exit. Obvious portals of exit include the respiratory tract, blood vascular system, skin, and mucous membranes, as well as the gastrointestinal and genitourinary tracts. In addition, contact of patient care supplies and equipment with any portal of exit will invariably result in potential contamination and the subsequent possibility of disease transfer.

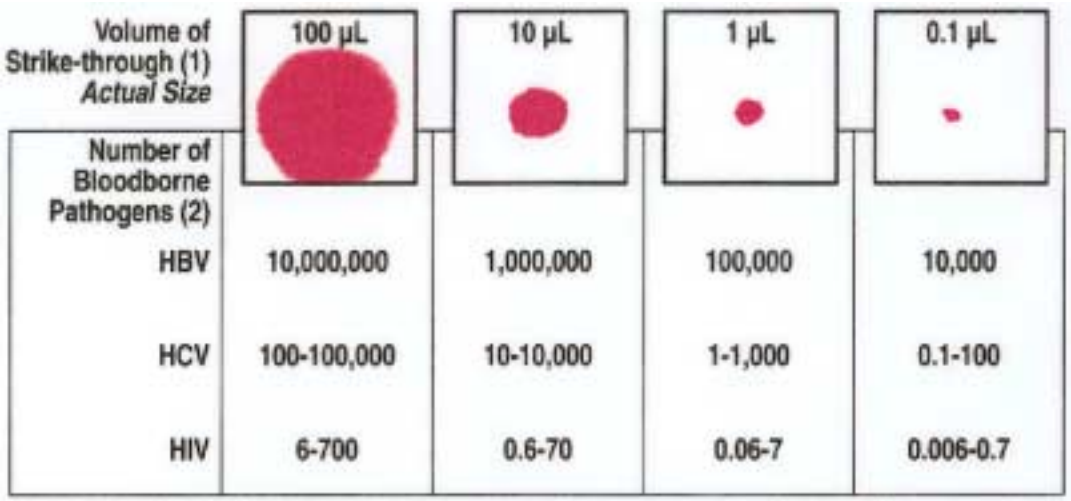

Figure B.2—Bloodborne pathogen strike-through conversion chart

Figure B.2 converts the amount of strike-through to the amount of potential bloodborne pathogen contamination. The four spots at the top were formed from premeasured droplets of synthetic blood and are marked in microliters ranging from 100 µ to 0.1 µ. Listed on the left are the three primary bloodborne pathogens: HBV, HCV, and HIV. The approximate number of infectious units that could be present in each spot, based on documented whole blood concentrations in infected patients, is shown for each type of virus; this data was derived from Bradley (1984), Ho et al. (1989), and Shikata et al. (1977). A recent study on transmission of bloodborne pathogens to health care workers found serum concentrations of HBV, HCV, and HIV to be as high as 10^8, 10^6, and 10^3 viral particles per milliliter, respectively (Lanphear, 1994). (Figure courtesy of W.L. Gore & Associates, Inc.)

NOTE 1—Volume of a red 40 dyne/cm synthetic blood delivered to white blotter paper.

NOTE 2—Based on documented whole blood concentrations in infected patients.

B.2.4 Mode of transmission

Although several potential mechanisms for transmission exist, the main mode of disease transfer involves contact transmission, either through direct or indirect contact with the patient or droplet spread via contact with exhaled respiratory secretions. Direct-contact transmission primarily involves person-to-person spread such as contact with the unwashed hands of a health care worker. Indirect-contact transmission can be the result of contact with a contaminated intermediate object such as a catheter, dressing, or surgical instrument. Droplet spread occurs through contact of the conjunctivae or mucous membranes of the nose or mouth with large (> 5 microns) droplets of respiratory secretions. Such droplets are generated primarily during coughing, sneezing, or talking. Typical examples of illnesses transmitted in this manner include streptococcal pharyngitis, mumps, and influenza.

Three additional means by which diseases can be transmitted are airborne, vehicular, and vector transmission. Airborne transmission occurs by means of the dissemination of either very small (< 5 microns) droplet nuclei resulting from respiratory secretions or dust particles containing the infectious agent. Typical diseases transmitted in this manner include tuberculosis, measles, and chicken pox.

Vehicular transmission involves the spread of disease-causing organisms through some secondary route, usually environmental objects such as contaminated medications or antiseptics (e.g., eyedroppers, multidose vials), food (e.g., hepatitis A or staphylococcal food poisoning), or water (e.g., giardiasis). Such diseases are very rarely the result of health care delivery.

Vector transmission involves the spread of pathogenic agents through secondary, animate hosts such as insects and rodents or other small animals. Typical examples of vectorborne diseases include malaria, rabies, plague, and Lyme disease. As with vehicular transmission of disease, vector transmission associated with the delivery of health care is extremely rare, if not nonexistent, in the United States.

B.2.5 Portal of entry

The fifth link in the chain of infection is a suitable portal of entry. The avenues for gaining entry into the body are, in most instances, identical to the portals of exit. It is important to understand that each of these portals is usually peculiar to given diseases and, for any given disease, there is usually a very specific portal of exit and entry. For example, tuberculosis and influenza involve only the respiratory tract and typhoid fever the gastrointestinal tract. Hepatitis B involves transmission by blood. Most infectious diseases and conditions require very specific portals of both entry and exit.

B.2.6 Susceptible host

The last link is a susceptible host, someone who lacks effective resistance to a given pathogenic agent. A variety of host factors must be present before infection can occur. Very few organisms can gain entrance through normal intact skin. Most require some breach in skin integrity. Other less obvious lines of defense include tears, gastric acid, and the cilia of the nose and upper respiratory tract. One's ability to mount a local inflammatory response provides yet another nonspecific host defense mechanism. Patients who are immunocompromised (e.g., the very young, the elderly, those who are undergoing immunosuppressive therapy, those with disorders of the immune system) are susceptible hosts.

B.3 Barrier protection and protective clothing

Protective clothing is often used to limit or prevent contact transmission of microorganisms. Strategies employed in the laboratory evaluation of protective clothing materials and the resulting understanding of performance expectations are very important when deciding which products are suitable for which applications. Such strategies need to consider both the modes of transmission (e.g., liquid-borne, aerosol-borne) and the perceived risk associated with varying types of microorganisms (e.g., viruses, bacteria, fungi). It is extremely difficult to duplicate the myriad physical, chemical, and thermal stresses placed on protective clothing in an actual setting. Nonetheless, the goal of laboratory testing is to provide information that will allow a realistic estimation of the performance of protective clothing during actual use.

NOTE—The FDA maintains a list of recognized standards applicable to protective clothing and barrier integrity testing. This list can be accessed via the Internet at <http://www.fda.gov/cdrh/stdsprog.html>.

Annex C
(informative)

Selection and use of chemical disinfectants

C.1 Introduction

This annex describes factors to consider in the selection of a chemical disinfectant for a particular application.

C.2 Categories of items to be disinfected

Medical and surgical materials (i.e., instruments and other medical devices and equipment) may involve a significant risk of transmitting infection to patients or health care personnel if not properly decontaminated and then disinfected or sterilized.

The CDC describes three categories of devices in terms of risk of infection and the level of disinfection or sterilization needed after decontamination and before patient use; these categories are based on Dr. E. H. Spaulding's 1972 classification of medical devices (Garner and Favero, 1985). This information was updated in Favero and Bond (1991) and Favero and Bond (2001) to include a fourth category.

a) **Critical items.** The risk of acquiring an infection if these instruments and devices are contaminated is substantial. Critical items are instruments or devices that are intended to come into contact with breached skin or compromised tissue (i.e., tissue that has lost natural barrier integrity or is damaged or injured); invasive products that enter normally sterile tissue; products with claims of sterile fluid pathways; and surgically implanted devices. Examples of critical items are surgical instruments, needles, transfer forceps, cardiac catheters, implants, inner surface components of extracorporeal blood-flow devices such as heart-lung machines and blood oxygenators, and the blood compartments of hemodialyzers. Sterility at the time of use is required for these items; consequently, one of several accepted sterilization procedures is generally recommended (Garner and Favero, 1985; Favero and Bond, 1991; Favero and Bond, 2001).

b) **Semicritical items.** Instruments and devices in the second category are classified as semicritical in terms of the degree of risk of infection. Examples are noninvasive flexible and rigid fiberoptic endoscopes; endotracheal and aspirator tubes; bronchoscopes; laryngoscopes; respiratory therapy equipment; cystoscopes; vaginal specula; and urinary catheters. Although these items come into contact with intact mucous membranes, they do not ordinarily penetrate body surfaces. If steam sterilization can be used, it is often cheaper to sterilize many of these items, but sterilization is not absolutely essential; at a minimum, a high-level disinfection procedure that can be expected to destroy some bacterial spores, all ordinary vegetative microorganisms, most fungal spores, tubercle bacilli, small or nonlipid viruses, and medium-sized or lipid viruses is recommended. In most cases, meticulous physical cleaning followed by an appropriate high-level disinfection treatment gives the user a reasonable degree of assurance that the items are free of pathogenic microorganisms (Garner and Favero, 1985; Favero and Bond, 1991; Favero & Bond, 2001).

c) **Noncritical items.** Instruments and devices that come into direct contact with the patient and normally only touch intact skin are in the third category. Such devices include surgical face masks, blood pressure cuffs, most neurologic and cardiac diagnostic electrodes, and certain surfaces of roentgenographic machines. These items rarely, if ever, transmit infections directly to patients. Consequently, depending on the particular item and degree of contamination, washing with a detergent and warm water may be appropriate (Garner and Favero, 1985; Favero and Bond, 1991; Favero and Bond, 2001).

d) **Environmental surfaces.** Items in this added category carry the least risk of infection transmission but may contribute to secondary cross-contamination by hands of health care workers or contact with medical instruments that will subsequently come into contact with patients. Environmental surfaces consist of the variety of surfaces that usually do not come into contact with patients or, if they do, only with intact skin. These surfaces can be divided into two major subdivisions: (1) medical equipment surfaces such as frequently touched adjustment knobs or handles on hemodialysis machines, roentgenographic machines, instrument carts, or dental units; and (2) housekeeping surfaces such as floors, walls, table tops, window sills, and so forth. As with noncritical instruments and devices, surfaces of medical equipment require simple cleaning with a detergent and warm water or, depending on the equipment surface and nature and degree of contamination, cleaning with a detergent germicide, or cleaning with soap and water followed by application of a low- to intermediate-level chemical disinfectant to achieve the level of safety needed. Housekeeping surfaces have the least potential for cross-contamination. These surfaces are maintained in a state of visible cleanliness by using water and a detergent or hospital-grade disinfectant/detergent

designed for general housekeeping purposes. All spills of blood and other potentially infectious body fluids or laboratory cultures should be cleaned with an intermediate-level chemical disinfectant (Favero and Bond, 1991; Favero and Bond, 2001).

The above categorization of patient-care items, coupled with knowledge of the antimicrobial activity of various types of disinfectants, facilitates the selection of an appropriate liquid chemical disinfectant. The choice of disinfecting method should be made based on the device manufacturer's instructions for use, how the device will contact the next patient, the physical configuration (cleanability) of the device, type and degree of contamination after use, physical or chemical stability of the device, and ease or difficulty in removing (rinsing, aerating) the chemical agent after the necessary exposure time. As part of the quality assurance program, users should periodically reassess the intended use and appropriate category of patient-care items.

C.3 Activity levels of disinfectants

The chemical agents found in disinfectants are sometimes classified as high-, intermediate-, or low-level disinfectants based on their ability to kill or inactivate vegetative bacteria, the tubercle bacillus, bacterial spores, fungi, and viruses.

The user who is choosing a product for a particular application might find the published descriptions of the effectiveness of various chemical agents quite confusing. This is particularly true for intermediate- and low-level disinfectants. One of the factors that determines the ability of a chemical agent to kill or inactivate microorganisms is the concentration of the chemical. For example, glutaraldehyde in very low concentration will inactivate certain types of viruses, whereas a much higher concentration is required to inactivate other types of viruses. It is also true that some chemical agents are not capable of killing certain microorganisms under practical conditions; that is, at reasonable temperatures, concentrations, and exposure times.

The biocidal effectiveness of chemical agents is described in several ways: as data on the chemical agent with no mention of brand names or specific product formulations; as label claims supported by technical data for a particular product formulation that contains the chemical agent; and as the results of controlled studies by independent parties. The first type of information is a guide to the expected efficacy of the active ingredient shown on the product label. To determine if the chemical agent in a product formulation will provide the level of decontamination required, the user should consult both the label claims and the current, relevant professional literature.

The CDC's 1985 *Guidelines for Handwashing and Hospital Environmental Control* (Garner and Favero, 1985) recognized three levels of disinfection (Table C.1) based on the work of Dr. E. H. Spaulding. If sterilization is not being performed, the CDC recommends high-level disinfection for patient-care items that will come into contact with intact mucous membranes and do not normally penetrate body surfaces. Intermediate- or low-level disinfection is considered suitable for noncritical items that come into direct contact with the patient and normally only touch intact skin.

NOTE—The unconventional agent that causes Creutzfeldt-Jakob disease (CJD) might not be inactivated by a high-level disinfection procedure; in fact, this agent is resistant to most commonly-used sterilization methods. See Favero and Bond (2001) and Rutala and Weber (2001) for guidelines on the decontamination of items exposed to CJD.

Table C.1—Levels of disinfection according to type of microorganism

	Bacteria				Viruses	
Level	**Vegetative**	**Tubercle bacillus**	**Spores**	**Fungi[1]**	**Lipid (medium)**	**Nonlipid (small)**
High	+[2]	+	+[3]	+	+	+
Intermediate	+	+	±[4]	+	+	±[5]
Low	+	–	–	±[6]	+	–

[1] Includes asexual spores, but not necessarily chlamydospores or sexual spores.

[2] Plus sign (+) indicates that a killing effect can be expected when the normal use-concentrations of chemical disinfectants or pasteurization are properly employed; a negative sign (–) indicates little or no killing effect.

[3] Only with extended exposure times are high-level disinfectant chemicals capable of killing high levels of bacterial spores in laboratory tests; they are, however, capable of sporicidal activity.

[4] Certain intermediate-level disinfectants (e.g., hypochlorites) can be expected to exhibit some sporicidal action; others (e.g., alcohols, phenolics) have no demonstrated sporicidal activity.

[5] Some intermediate-level disinfectants might have limited virucidal activity.

[6] Some low-level disinfectants might have limited fungicidal activity.

C.4 Labeling of disinfectant products

The labeling of liquid chemical sterilants/high-level disinfectants that are intended to process reusable critical and semicrital medical devices is regulated only by the FDA. The labeling of these devices provides a guide for users in selecting the activity level of disinfection. Under FDA regulation, the labeling for liquid chemical sterilants/high-level disinfectants must provide information relating to safe and effective use. The FDA has described guidance for basic labeling in FDA (1996) and FDA (2000a). The labeling for liquid chemical germicides should identify the active ingredients and their concentrations, and provide information on measuring the MRC or MEC prior to use, the required contact time, use temperature, reuse pattern, material/device compatibility, necessary PPE, stability, and shelf life. It also should provide any additional information needed by the user for the safe and effective use of the product. The labeling includes a package insert containing all of the above information, as well as any supplemental information for the user. The FDA labeling requirements for these products rely on the broader disinfection terms defined by Spaulding (1972) to indicate product effectiveness, so the terms used in EPA-mandated labeling ("virucidal," "fungicidal," "bactericidal," and "tuberculocidal") have been phased out. Additionally, under FDA labeling policy, reference to specific diseases such as tuberculosis and AIDS is not permitted unless effectiveness has been shown in clinical trials. The FDA guidance document, *Content and format of premarket notification [510(k)] submissions for liquid chemical sSterilants/high level disinfectants* (FDA, 2000a), describes FDA regulation and requirements in detail.

General-purpose disinfectants that are intended to process noncritical medical devices and equipment surfaces or preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high-level disinfection are Class I medical devices and are exempt from the FDA's 510(k) premarket notification requirements. These general-purpose disinfectants are regulated by EPA under FIFRA. The EPA-required labeling includes an EPA registration and establishment number, the product name, and the EPA-approved biocidal claims (e.g., "fungicidal," "bactericidal"). FIFRA requires that the label for a disinfectant product include the product name, net contents, manufacturer's EPA establishment number, an ingredient statement identifying the active chemical agent in the formulation, directions for use, recommendations for use, the name and address of the manufacturer or distributor, and safety and precautionary information.

Sometimes a product is designated both a disinfecting and sterilizing solution, which indicates that it is both a disinfectant and a chemical sterilant. Usually, the exposure times for disinfection and sterilization are different, and these times are shown on the label under the directions for use. The directions for use also indicate the temperature at which the solution must be used in order to kill the microorganisms listed in the recommendations for use.

The safety precautions address such matters as the need for eye protection or gloves when the user is handling the solution. A warning section might state that the solution can cause eye irritation and might contain first-aid recommendations. A section on materials compatibility could identify materials or devices with which the solution is incompatible.

The ingredient statement identifies the active ingredient in the formulation and its percentage or strength.

The recommendations for use indicate the reuse pattern and use-life. For example, the label could state that the use-life is 28 days after activation and the solution is reusable for 28 days.

C.5 Criteria for selecting a chemical disinfectant

Chemical disinfectants vary in their ability to kill specific types and numbers of microorganisms. To choose the appropriate chemical disinfectant for a particular application, it is necessary to determine the antimicrobial activity required (both in terms of types of organisms to be killed and reduction levels) and examine the manufacturer's label claims and technical information regarding antimicrobial activity.

The product label must be examined for information on the use-pattern, use-life, and storage life of the product. It is important to distinguish between the use-life of a disinfectant and its use-pattern. The use-life commonly applies, but is not limited, to disinfectant products that require the mixing of two ingredients for activation. Once a disinfectant solution is mixed, there might be a limited period of time during which the activated solution can be used; that time is its use-life and should be shown on the label. The use-life can be 1 day, 14 days, 28 days, or whatever period is indicated on the label. The actual use-life could be shorter than stated on the label because dilution, the presence of organic material, or residual detergent could alter the effectiveness of the solution as it is being used (see C.6).

The use-pattern refers to how many times the solution can be used; it may be used one time only or it may be reused for the period of its use-life. The use-pattern also can be expressed in terms of the number of disinfection cycles. The storage life, which is determined by the expiration date and could be a year or more if the product is stored according to the manufacturer's instructions, is the time period after which the unused and/or non-activated product is no longer deemed effective.

Both the manufacturer of the disinfectant and manufacturer of the device to be decontaminated should provide information on materials compatibility. The data should support the safety of a solution with respect to the materials from which a particular device is constructed (e.g., metals, alloys, plated metals, plastics, and combinations thereof). The information should state whether materials compatibility is affected by exposure time, exposure temperature, or concentration. Certain chemicals, especially when dissolved in water, are capable of corroding metals; this is particularly true of strong oxidizing agents such as products that contain chlorine. Certain metals in contact with one another tend to corrode more rapidly than each metal alone. Certain plastics can become brittle if exposed to particular chemical agents. Some items requiring decontamination are very expensive (e.g., endoscopes), so the user should contact the manufacturer of the device to determine if the materials in the device have been tested and found to be compatible with the disinfectant product.

C.6 Quality control in chemical disinfection

The user should be aware of factors that can alter the effectiveness of a chemical disinfectant:

a) **Use-pattern.** Only those disinfectants labeled for reuse should be reused. A reuse claim on the product label indicates that the manufacturer has documented that, after a simulated reusing of the disinfectant for the period of time specified in the manufacturer's study, the disinfectant was effective in killing the microorganism types shown on the label. Use-pattern is event-related, not time-related.

b) **Use-life.** The use-life stated on the label must not be exceeded. Use-life is event-related and time-related. The use-life could be shorter than what is stated on the label because of events that alter the concentration of the liquid chemical germicide.

c) **Bioburden.** The process has been tested against a known number of microorganisms, and its success depends on the cleanliness of the items to be processed.

d) **Water and extraneous materials.** Organic matter in the form of serum, blood, pus, or fecal material can protect microorganisms and might consume or inactivate the active chemical agent in the disinfectant. Soaps, detergents, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water also can interfere with the effectiveness of the disinfectant. The manufacturer of the disinfectant should be consulted for information on the appropriate water, soaps, and detergents to be used in conjunction with the disinfectant.

   NOTE—The disinfectant manufacturer might not have included organic matter or extraneous materials in challenge tests of antimicrobial efficacy. Even if simulated soil was used to challenge the disinfectant (see AAMI TIR12), the amount of organic or foreign material used in the testing might not be comparable to that encountered in actual use conditions.

e) **Dilution.** The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be significant in the long-term use and reuse of a chemical disinfectant and potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. An MEC or MRC statement is required by the FDA. As part of a health care facility's quality control program, high-level disinfectants/sterilant solutions such as glutaraldehyde should be monitored upon activation and before each use in order to detect unexpected dilution of the solution.

f) **Temperature.** The antimicrobial claims stated on the product label are determined according to exposure time and temperature. For example, the label might state: "To kill *M. tuberculosis*, immerse the device for 1 hour at 25 °C (77 °F)." This label claim will have been fully documented. If the temperature of the solution is at any time lower than the temperature indicated on the product label, then complete disinfection might not be achieved during the prescribed time period. On the other hand, the temperature should not be high enough for the active ingredients to evaporate appreciably. A thermometer should be used to monitor the solution temperature.

g) **Evaporation and light.** Evaporation can occur from a solution in an uncovered container. If the chemical agent is more volatile than the diluent (a gas dissolved in water is more volatile than water), then loss of the agent by evaporation can be very important. Chlorine products are especially susceptible to evaporation effects. Exposure to light also can affect chlorine products and disinfectants.

h) **pH.** Disinfectants can be formulated over a range of pH values, depending on the chemical agent used. Some agents are more effective in killing microorganisms under alkaline conditions (a pH higher than 7), while others work best under acidic conditions (a pH lower than 7). The introduction of detergents to the disinfectant solution, which can occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness.

i) **Device characteristics.** A disinfectant solution is only effective if it can contact all surfaces of the item to be disinfected. The FDA recommends that medical device manufacturers perform testing that assesses the compatibility of the device with cleaning and defoaming agents and materials, including in-use testing of devices with complex design configurations that could impede penetration by cleaning and disinfectant agents.

j) **Rinsing.** Inadequate quality of the rinse water used could result in recontamination of the medical device. If the medical device is required to be sterile and undergoes liquid chemical sterilization, then it should be rinsed with sterile water. In other cases, tap water may be used to rinse an item after it has undergone high-level disinfection. This water should at least be of potable quality, and the final drying step should include flushing of all channels with alcohol, followed by purging the channels with air (to remove the alcohol).

C.7 Safety considerations in chemical disinfection

The user should consult the MSDS supplied by the disinfectant manufacturer and observe the recommended safety precautions. In general, the following factors should be considered:

a) adequate ventilation and, if necessary, a vented hood in the disinfection area to evacuate the chemical vapors from glutaraldehyde and other products;

b) the use of covered containers for the disinfectant solution, when appropriate;

c) appropriate procedures and protective clothing for the user, such as gloves, eye protection, surgical face masks, and liquid-resistant gowns or aprons, as required by OSHA (29 CFR 1910.1030); and

d) adequate rinsing of devices with sterile, distilled water after disinfection.

OSHA has established occupational exposure limits for several agents used in chemical sterilants and disinfectants. Employers are required by law to ensure compliance with these limits by implementing engineering controls, defining procedures for safe employee work practices, establishing medical surveillance programs, providing respiratory protection, and taking other measures to the extent specified by OSHA. In addition, product manufacturers may be subject to certain labeling requirements.

Limits established by OSHA for airborne contaminants, including some liquid chemical sterilant/HLD and gaseous sterilant chemicals, are set forth in 29 CFR 1910.1000. Separate standards limiting occupational exposure to EO and formaldehyde are set forth in 29 CFR 1910.1047 and 29 CFR 1910.1048, respectively. In 1989, OSHA adopted a final rule for air contaminants in which permissible exposure limits (PELs) for hundreds of chemicals were revised or added to the air contaminants standard in 29 CFR 1910.1000. These limits were based largely on the recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH). In 1992, the 11th Circuit Court of Appeals ruled that OSHA did not sufficiently demonstrate that the new PELs were necessary or feasible. As a result of the Court's decision to vacate the new limits, OSHA was forced to return to the original limits published in 1971. However, OSHA can invoke the general duty clause of the Occupational Safety and Health Act of 1970 to regulate employee exposure to hazardous chemicals for which OSHA-established limits do not exist. For example, before 1989, the air contaminants standard did not include exposure levels for glutaraldehyde, and there are no current OSHA-established exposure limits for glutaraldehyde. However, OSHA has invoked the general duty clause to regulate employee exposure and has recommended that exposures be controlled to the ACGIH-recommended TLVs for glutaraldehyde (Table C.2). Additionally, states with federally-approved state OSHA programs may independently decide to enforce the PELs originally promulgated in the 1989 rule for air contaminants.

Limits on occupational exposure to chemical agents are commonly defined in terms of the maximum amount of chemical to which an employee can be exposed over a specified period of time. For example, OSHA mandates PELs calculated as an 8 hour time-weighted average (TWA) exposure. For some chemicals, a "short-term exposure limit" (STEL) which is based on a 15 minute exposure has been established. For certain chemicals, including EO and formaldehyde, OSHA has established an "action level" (AL), which is the 8 hour TWA exposure level above which employers must initiate certain compliance activities such as periodic employee exposure monitoring and medical surveillance. "Excursion limit" (EL) is a term adopted by OSHA specifically for defining a short-term exposure limit for EO. Like a STEL, an EL is the maximum 15 minute exposure to which a worker may be subjected. ACGIH, a private professional organization, recommends "threshold limit values" (TLVs), defined in terms of 8 hour TWAs, 15 minute STELs, and/or ceiling limits, for a large number of chemical substances and physical agents.

Table C.2 lists chemical agents found in chemical sterilants and disinfectants and the exposure limits currently mandated by OSHA and recommended by ACGIH. Additional information on OSHA requirements can be found on the OSHA Internet home page at <http://www.osha.gov>. Additional information on ACGIH recommendations can be found in ACGIH (2001).

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

Chemical agent	OSHA PEL	ACGIH TLV
Acetic acid	10 ppm TWA 25 mg/m^3 TWA	10 ppm TWA 15 ppm STEL
Alcohol	Various*	Various*
Formaldehyde	0.75 ppm TWA 2 ppm STEL 0.5 ppm AL	0.3 ppm ceiling
Glutaraldehyde	None**	0.05 ppm ceiling
Hydrogen peroxide	1 ppm TWA 1.4 mg/m^3 TWA	1 ppm TWA
Ortho-phthalaldehyde	None	None
Peracetic acid	***	***

* Various types of alcohol are used in sterilant formulations, and the occupational exposure limits vary. Refer to the product label for the active ingredients and consult the latest ACGIH recommendations and OSHA regulations.

** No exposure limits have been established by OSHA. However, OSHA can invoke the general duty clause of the Occupational Safety and Health Act of 1970 to regulate exposure to glutaraldehyde and has recommended that the ACGIH TLVs be followed.

*** Peracetic acid exists in equilibrium with hydrogen peroxide and acetic acid, so occupational exposure limits for both hydrogen peroxide and acetic acid apply.

Annex D
(informative)

Thermal disinfection

D.1 Introduction

This annex describes factors to consider when applying thermal (hot water) disinfection processes to the decontamination of reusable medical devices. Thermal disinfection selectively destroys microorganisms. The number and type of microorganisms killed on clean items, and thus the level of decontamination achieved, depend on exposure time and exposure temperature.

D.2 Microbial destruction by heat

Microbial resistance to thermal death depends on the state of the microorganism; vegetative bacteria are much easier to kill by heat than spores. The inherent resistance of different species of microorganisms also varies; for example, certain species have a waxy coating that provides brief protection against heat. In general, bacterial spores and certain viruses are the most resistant to heat, followed by most fungi and some viruses; vegetative bacteria are the least resistant.

D.3 Items suitable for thermal sanitization/disinfection

Thermal sanitization and disinfection equipment employ hot water temperatures of 60 °C to 95 °C (140 °F to 203 °F). (By contrast, sterilizers employing saturated steam typically operate at temperatures of 121 °C to 140 °C (250 °F to 285 °F).) Thermal sanitization equipment generally operates at somewhat lower temperatures or for shorter exposure times than disinfection equipment, but there is no agreement on precisely when sanitization stops and disinfection begins.

Instruments, devices, and equipment that are heat- and moisture-stable may be decontaminated by thermal sanitization or disinfection processes. The choice of method depends on factors such as the level of risk to personnel and patients, the ease with which an item can be cleaned and inspected, and the relative cost-effectiveness of using washer-sanitizers or washer-disinfectors versus washer-sterilizers or steam sterilizers.

D.4 Manufacturers' instructions

The user should carefully follow the operating instructions supplied by the thermal disinfection equipment manufacturer and any instructions supplied by the manufacturer of the device to be decontaminated. If the equipment provides a washing or cleaning process, the following factors also should be taken into account: the type of soil, quality of the water, force and direction of the water, choice of cleaning agent, exposure time, and water temperature.

D.5 Quality control in thermal disinfection

Time and temperature should be monitored. Some types of equipment provide timers and temperature gauges for this purpose. Temperature-sensitive indicators also are available to monitor the internal temperature achieved during processing.

D.6 Safety considerations in thermal disinfection

Personnel should be careful to avoid burns when removing hot items from thermal sanitization or disinfection equipment. Wet items can drip, which can lead to slippery floors or work surfaces.

Annex E
(informative)

Devices returned to the manufacturer

E.1 Introduction

A medical device that has been used in patient care is contaminated with potentially infectious microorganisms and thus could pose hazards to health care and other personnel if the device is not handled and decontaminated properly.

The main text of this recommended practice addresses the decontamination of devices intended for reuse in patient care within a health care facility. There is a need, however, for additional guidance on the safe handling and decontamination of devices that are returned to the manufacturer for servicing or evaluation of suspected malfunctions. Such devices can pose health hazards to postal/shipping personnel and the manufacturer's employees. Special considerations also apply to devices returned to third parties (e.g., test laboratories) and samples, loaners, and investigational devices that might be returned to the manufacturer or transferred from hospital to hospital.

This annex is intended to provide assistance to device manufacturers, health care personnel, and third parties in the development of appropriate handling and decontamination procedures.

E.2 Overview

After use in patient care, a medical device might be returned to the manufacturer for servicing or the evaluation of a suspected malfunction or failure. Ideally, such devices should be decontaminated by the user before they are shipped. In some instances, however, a decontamination procedure could obscure the cause of the malfunction or failure and thus inhibit the manufacturer's follow-up evaluation. In other instances, the device might not be capable of being appropriately decontaminated at the user facility, or health care personnel could simply neglect to decontaminate the device properly. Manufacturers should establish procedures for the protection of their personnel and provide appropriate instructions to users for the handling, decontamination, and shipment of devices that require servicing or failure investigation. For their part, health care personnel should develop their own procedures for the handling and decontamination of such devices in accordance with the manufacturer's instructions. Both manufacturers and health care facilities must comply with OSHA regulations limiting occupational exposure of employees to bloodborne pathogens (29 CFR 1910.1030).

NOTE—The guidelines provided here are written in the context of devices returned to manufacturers for servicing, repair, or failure investigation. However, the same considerations apply to devices sent to testing laboratories or other third-party organizations.

E.3 Manufacturer's instructions to the user

Manufacturers that require their devices to be returned from the field to facilitate servicing or investigate a device failure are obliged to provide the user with specific, written instructions for the safe handling and return shipment of each device. These instructions should include at least the information listed below. (Additional guidelines on the following topics are provided in subsequent sections of this annex.)

— Who to contact at the company for assistance

— The recommended method of decontamination, with disassembly instructions if required, and any limitations associated with it

— Any actions that could result in the inadvertent destruction of evidence pertaining to the cause of the suspected failure or malfunction

— Directions for the documentation that should accompany the device

— Recommended instructions for packaging, labeling, and shipping, including instructions to verify compliance with local regulations

The manufacturer should ensure that adequate resources are in place to assist users in complying with the manufacturer's requirements. That is, the manufacturer should have adequate personnel, with identified responsibilities, to handle inquiries about devices to be returned and supply information. The manufacturer can choose to provide return product kits which include written instructions approved by the manufacturer, data forms containing all information necessary for processing the returned device, appropriate shipping containers to protect

the device during transport, and all hazard labels. The manufacturer is responsible for verifying that the recommended decontamination procedures are effective for the device.

E.4 User responsibilities

E.4.1 General

Users are responsible for verifying that appropriate information is supplied with the device. If no instructions or incomplete instructions are provided, the user should attempt to contact the manufacturer for return authorization and further instructions. The user is also responsible for processing the device according to the manufacturer's recommendations. All documentation requested by the manufacturer should be accurately completed. In addition, the user should identify for the manufacturer the nature of the device malfunction or failure and provide information on who to contact at the user facility. If the user is aware of additional information that might assist the manufacturer in servicing or evaluating the returned device or could suggest the need for special handling of the device at the manufacturer's facility, this information should be provided; for example, the user should notify the manufacturer if the device has been exposed to a known infectious agent. All documentation pertaining to the returned device should be packaged separately from the device but provided in or on the same shipping container.

E.4.2 Decontamination at the health care facility

Appropriate handling and/or decontamination of a medical device will depend on whether the device is being returned to the manufacturer for repair, service, or failure investigation.

The user should contact the device manufacturer for handling and/or decontamination methods appropriate for the device in question.

The user should document how the device was used in patient care, how it was decontaminated, the date of processing, and a means of identifying the person who decontaminated the device. (If the device is being returned to the manufacturer for failure investigation, it might be appropriate to photograph or draw the device before decontaminating it.) This information, along with an explanation of the reason for returning the device to the manufacturer and an accurate description of any defects, should accompany the device when it is shipped. This documentation should be positioned so as to protect it from contamination and allow easy retrieval by the manufacturer.

E.4.3 Packaging, labeling, and shipment to the manufacturer's facility

E.4.3.1 General

Whether or not it has been subjected to a decontamination process, a contaminated device to be returned to the manufacturer should be placed in a securely sealed and leakproof primary container or as specified by the device manufacturer. The package must be clearly identified as contaminated material and packaged, labeled, and shipped in accordance with the manufacturer's instructions, with the requirements of the carrier (U.S. Postal Service or private carrier), and with the applicable DOT regulations (49 CFR 170–178). In most cases, it is advisable to pack the medical device while it is dry. However, there may be special circumstances in which the device may need to be kept moist. If it is to be kept moist, the user should request from the manufacturer information on how to ship the device in the moist state.

E.4.3.2 Postal regulations

Postal regulations require that sharps and other medical devices be sent using First Class or Priority mail in packaging that meets the specifications described later in this section; all packaging used for the mailing of sharps be "type-tested" and certified by an independent organization; and the package bear a U.S. Postal Service authorization number on a label that cannot be removed intact. Appropriate documentation should be affixed to the outer shipping container; this documentation should include (in case of package damage or leakage), a 24-hour telephone number at the destination facility. Packages also should be labeled with a complete return address and the proper shipping name of the contents. Section 124.38 of the *Domestic Mail Manual* contains the complete requirements for the shipping of sharps and other medical devices.

If the device to be returned is a sharp, then the primary container should be puncture-resistant and placed into a watertight secondary containment system. This secondary containment system may consist of more than one component; however, if one of the components is a plastic bag, the bag should be at least 3 mils thick and reinforced with a fiberboard sleeve. The primary container and/or secondary containment system should be packed in an outer shipping container designed to prevent breakage during ordinary processing and comprised of at least 200-pound-grade corrugated material or a material of equivalent strength. More than one primary container may be sent in a parcel; however, the net contents of liquid in each primary container should not exceed 50 milliliters, and enough absorbent material should be present to absorb three times the total volume of liquid in the secondary containment system or outer shipping container.

Coolant material, if used, should be packaged in such a way that if it melts or condenses, the liquid produced will not escape from the outer shipping container. If ice or dry ice is used, shock-absorbent material should be placed so as to immobilize the inner container as the ice or dry ice melts or sublimates. Packages containing dry ice should be packed in containers that permit the venting of carbon dioxide gas, marked DRY ICE, and labeled with the net weight of the dry ice.

E.4.3.3 DOT regulations

The pertinent DOT regulations are Hazardous Materials Regulation 126 (HM126) and Hazardous Materials Regulation 181 (HM181). These regulations are codified in Title 49, Parts 170 through 178, of the *Code of Federal Regulations*. Among other things, the DOT requires formal training of all persons who are in any way involved in the shipping process, including anyone who prepares hazardous items for shipment or shipping documents. Several levels of training are specified in the law, ranging from "general awareness" to "function-specific." The required training must include safety issues and be documented. If training records are not complete, the shipper is subject to significant penalties.

The shipper is responsible for the correct packaging and labeling of items entering interstate commerce. If the manufacturer provides inadequate or incorrect shipping instructions, the law still holds the shipper responsible. Thus, the shipper must take the responsibility for making certain that the documents and packaging are correct. The shipper may rely on the manufacturer's information as a starting point, but should take some documented action to verify that the information is correct. The law places personal responsibility and liability on persons who improperly ship hazardous materials and/or on the individuals responsible for supervising these persons. Depending on the severity of the violation and pattern of violations, personal fines and/or imprisonment can be assigned to anyone from the shipping clerk to the chief executive officer.

E.5 Receiving at the manufacturer's facility

When a problem appears in clinical use of a device, the manufacturer might request that it be returned for investigation and resolution of the problem. Decontamination processes used in the health care facility might not be compatible with the device; for example, the decontamination process could melt the device, the chemical agents could react with materials used to construct the device, or the decontamination process might not be capable of rendering the device safe. For this and other reasons, a device being returned to the manufacturer from the clinical end user could be contaminated with disease-producing microorganisms. The OSHA regulations limiting occupational exposure to bloodborne pathogens (29 CFR 1910.1030) require that all employees who might come in contact with the contaminated device must apply universal (standard) precautions, including the wearing of PPE. In addition, the manufacturer is responsible for ensuring that all employees who will be handling the contaminated device (e.g., receivers, unpackers, laboratory personnel performing testing) receive the required educational preparation as prescribed by OSHA; this training must be documented. (It should be noted that not all disease-producing microorganisms are transmitted by blood, and varying levels of precautions could be needed, depending on the intended use of the device.)

Policies and procedures for the care and handling of contaminated devices should be specific (that is, compliance must be observable or measurable), incorporate the requirements established by OSHA, and address at least the following functions:

a) control of the receiving/unpacking area;

b) receipt of the contaminated device;

c) disposition upon receipt;

d) examination of accompanying paperwork;

e) use of PPE;

f) disposal of all contaminated materials, including the primary packaging, secondary packaging, and, once it has been examined, the device;

g) environmental controls (barrier walls, room with negative air flow, environmental chamber);

h) containment of the device once unpacked;

i) method of transport through the process;

j) area decontamination procedures;

k) exposure response; and

l) recordkeeping.

E.6 Cleaning, decontamination, and sterilization methods at the manufacturer's facility

If possible, the device should be decontaminated according to the manufacturer's established policies and procedures. If decontaminated, the device should then be placed in a clean container that is labeled to indicate that the device has been decontaminated.

The method of decontamination should render the device safe to handle regardless of the type of biological tissue that has come into contact with the device.

NOTE—In some cases, decontamination can interfere with failure investigation of a device. If so, the device must remain in a biohazard bag, and personnel handling the device must be safeguarded by appropriate PPE and engineering controls.

Other factors to take into account, some of which should be considered during product design, are:

a) the configuration of the device (the preferred disinfectant might not be able to penetrate all areas of the device that require decontamination);

b) the materials from which the device is fabricated (the materials in the device might be heat-labile or susceptible to damage by particular chemical disinfectants);

c) the cleanliness of the device (disinfectants and sterilants are only effective if the surfaces to be decontaminated are clean); and

d) the biocompatibility or safety of the disinfectant/sterilant and whether it can be completely removed prior to the next use, if applicable (whether the disinfectant/sterilant is toxic is also important from the standpoint of health risks to employees who have to inspect or test the returned device).

By considering these factors in the design phase, the manufacturer can address and pre-establish handling and decontamination instructions and verify them before production and release. Such care will protect both the user and manufacturer's employees.

Further information on decontamination is provided in the main text of this recommended practice. The properties of chemical disinfectants and sterilants are discussed in some detail in annex C and AAMI TIR7.

E.7 PPE at the manufacturer's facility

Personnel should wear appropriate PPE, commensurate with the degree of risk, when handling contaminated devices. Such attire may include gloves, gowns, laboratory coats, head and foot coverings, face shields or surgical face masks, eye protection, and respiratory protection. All reusable attire should be cleaned or sanitized regularly.

Gloves should be worn when there is a potential for direct skin contact with a medical device. Disposable decontamination gloves should be replaced as soon as their ability to function as a barrier is compromised; they should not be washed or disinfected for reuse. Heavy-duty, reusable decontamination gloves may be disinfected for reuse if the integrity of the gloves is not compromised; however, they should be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

Gowns, lab coats, aprons, or similar clothing should be changed whenever soiled and in accordance with the manufacturer's established procedures. Such clothing should not be worn outside of the immediate work area. Liquid-resistant clothing should be worn if there is potential for splashing or splattering of blood or other potentially infectious materials. Protective clothing should be liquid-proof if there is a possibility that attire might become soaked with blood or other potentially infectious material. Liquid-proof shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other body fluids.

E.8 Work practices for infection control at the manufacturer's facility

Handwashing facilities should be readily accessible to employees so that when their hands have been in contact with potentially infectious medical material, they can wash their hands as soon as possible after they remove gloves or other PPE. Antiseptic towels or alcohol-based, waterless, hand-hygiene agents can be used as an interim precaution until the employee can reach a handwashing area.

Once removed, contaminated protective attire and equipment should be placed in a clearly marked container or designated area for storage, washing, decontamination, or disposal. To determine when PPE should be used, the employer should evaluate the circumstances of potential exposure and significant employee risk.

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses should be prohibited in work areas where there is a risk of occupational exposure to chemical or biological materials. Food and drink should not be stored in places where infectious materials are located. Employees wearing PPE should not enter designated lunchrooms or break areas.

All procedures involving the handling of contaminated devices should be performed so as to minimize splashing, spraying, or aerosolization of infectious materials.

Work areas should be posted as restricted-access (including but not limited to access only to authorized personnel) due to the presence of infectious materials. If a work area is enclosed, the doors should be kept closed when personnel are working with potentially contaminated medical devices. Personnel working in these restricted occupational exposure areas must have received formal training as specified by OSHA (29 CFR 1910.1030), and documentation of this training must be kept on file.

Whenever there is a potential for contamination from a medical device, a warning sign incorporating the universal biohazard symbol should be posted on all access doors.

All activities involving potentially infectious aerosols (e.g., packaging, unpacking, and examination of contaminated devices) should be conducted in biological safety cabinets or physical containment devices. Such work should not be conducted on an open bench. Devices should be transferred to containment areas in leakproof, sealed containers.

All materials to be removed from a biological safety cabinet or other containment area should be surface sprayed or wiped with an appropriate disinfectant before removal.

A clearly written company policy should be established to specify the procedures to be followed for spills, accidents, and immediate cleanup of potentially infectious materials.

E.9 Housekeeping and waste disposal

During housekeeping and waste disposal procedures, personnel should wear appropriate PPE such as gloves, aprons, laboratory coats, and head and foot coverings. Face shields or surgical face masks, eye protection, and/or respiratory protection should be worn if there is potential for aerosol generation or splashing during cleanup (e.g., scraping).

All work sites should be maintained in a clean and sanitary condition. All equipment and work surfaces associated with the handling of contaminated devices should be decontaminated by cleaning and the application of an appropriate disinfectant after completion of procedures or as soon as is feasible. Immediate cleaning is essential, especially when surfaces are visibly soiled, after any spill of blood or other potentially infectious material, and at the end of the work shift.

Disinfecting solutions should be used in accordance with the solution manufacturer's instructions for preparation, contact time, length of effectiveness/expiration time, and disposal. If toxic vapors might be present, containers (e.g., pans) used for soaking equipment in disinfecting solutions should be placed in a system that will remove vapors, such as a ventilated fume hood or biological safety cabinet vented to the outside. Solutions of ethanol, isopropanol, sodium hypochlorite, or hydrogen peroxide can be poured down the sanitary sewer. Solutions of glutaraldehyde, formaldehyde, or iodophors should be properly discarded in accordance with the manufacturer's instructions and local regulations. Care should be taken to prevent fires when flammable disinfecting solutions are used (e.g., ethanol, isopropanol, 8 % formaldehyde/70 % ethanol or isopropanol).

Equipment and tools that can become contaminated from use during examination and/or repair of returned medical devices should be routinely cleaned and decontaminated after use and before servicing other medical devices (see D.6). Small hand tools such as forceps, hemostats, brushes, dust pans, and shears should be immersed in a disinfecting solution, or cleaned, wrapped, and sterilized. Appropriate disinfecting solutions include but are not limited to: 2 % glutaraldehyde, 8 % formaldehyde plus 70 % ethanol or isopropanol, 6 % hydrogen peroxide, 70 %–80 % ethanol or isopropanol, and iodophor disinfectants. (Iodophor formulations that are EPA-registered as disinfectants should be used, not iodophors formulated as skin antiseptics; the manufacturer's instructions for dilution and use should be followed.) Household bleach containing sodium hypochlorite also may be used. Bleach will not have label directions for this application. However, it can be effective, is readily available, and is inexpensive. Commercially available solutions are generally formulated at a concentration of 5.25 % v/v. A 1:10 dilution of the commercial product, freshly prepared with tap water for each application, should be used. The undiluted bleach should be stored in an opaque container, since light degrades its potency.

Large equipment that cannot be sterilized or soaked in disinfectant should be sprayed and/or wiped down on all exposed, potentially exposed, and/or contaminated surfaces with an appropriate disinfectant solution.

Bins, pails, cans, and other receptacles intended for reuse should be inspected, cleaned, and decontaminated on a regularly scheduled basis (at least daily), and cleaned and decontaminated immediately or as soon as possible upon visible contamination.

Any materials to be decontaminated at a site away from the work area should be placed in durable, leakproof containers, and the containers should be closed before being removed from the work area. Reusable sharps that are

contaminated with blood or other potentially infectious materials should not be stored or processed in a manner that requires employees to reach into the container by hand to retrieve the sharp.

Immediately after use, sharps should be placed in closable, puncture-resistant containers that are leakproof on the sides and bottom and labeled with an appropriate hazard warning. These containers should be located in the immediate area of use so that they are easily accessible. The containers should be replaced routinely and not allowed to overfill.

Broken, contaminated glassware should not be picked up directly with bare hands. The glassware should be cleaned up by mechanical means using at least a dust pan and brush, tongs, toweling, or forceps. Glass should be disposed of in a container the same as or similar to that used to confine other sharps.

All infectious waste should be disposed of in accordance with OSHA regulations (29 CFR 1910.1030) and other applicable federal, state, and local regulations.

Contaminated laundry should be handled as little as possible, with a minimum of agitation, bagged or contained at the point of use, and labeled as biohazardous or otherwise identified as requiring standard precautions. It should not be sorted or rinsed at the location of use but placed and transported in bags or containers that prevent soak-through or leakage of fluids to the exterior. Personnel who have contact with contaminated laundry should wear appropriate protective attire.

E.10 Device failure investigation

Observations and findings should be recorded orally for later transcription so that documents that could be subsequently handled by other departments will not be contaminated.

The documentation should include at least the following:

a) date received;

b) condition of shipping container(s);

c) shipping label information;

d) information received from the user;

e) visual condition of the device;

f) initial specific, pre-established investigational procedure implemented for the device; and

g) correlation, as appropriate, with MDR information required by the FDA.

The manufacturer should have policies and procedures in place for the retention of all documentation regarding the findings and the device. The policies and procedures should comply with FDA regulations promulgated under the Safe Medical Devices Act of 1990.

E.11 Documentation to the user

If the device is to be returned to the user, it should be accompanied by documentation of any decontamination procedures performed by the manufacturer, the servicing performed (e.g., any parts replaced), and, if applicable, the failure investigation (e.g., problems identified, suggested measures for preventing such problems in the future).

If the device is not to be returned to the user, the user should be informed of the results of the investigation.

Annex F
(informative)

Occupational exposure to bloodborne pathogens (29 CFR Part 1910.1030)[2]

§ 1910.1030 Bloodborne pathogens

(a) *Scope and Application.* This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) *Definitions.* For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means 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.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineering sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels, or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-Up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

[2] The regulation quoted here is current as of the publication date of this recommended practice. To check for any subsequent changes, refer to the *Code of Federal Regulations,* 29 CFR Part 1910.1030.

(2) The administration of medication or fluids; or

(3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means 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.

Other Potentially Infectious Materials means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is 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.

Production Facility means a facility engaged in industrial-scale, large-volume, or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV, but not in the volume found in production facilities.

Sharps with engineering sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means 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).

(c) *Exposure Control*—(1) *Exposure Control Plan*. (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) The exposure determination required by paragraph (c)(2);

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping of this standard; and

(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

(B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) *Exposure Determination*. (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure; and

(C) A list of all tasks and procedures or groups of closely related tasks and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) *Methods of Compliance*—(1) *General*. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) *Engineering and Work Practice Controls*. (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

(D) In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or other potentially infectious materials are present.

(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) *Personal Protective Equipment*—(i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered “appropriate” only if it does not permit blood or other potentially infectious materials to pass through or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee’s professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an

increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed, it shall be placed in an appropriately designated area or container for storage, washing, decontamination, or disposal.

(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves, such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for reuse.

(C) Utility gloves may be decontaminated for reuse if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary, then the employer shall:

(1) Periodically reevaluate this policy;

(2) Make gloves available to all employees who wish to use them for phlebotomy;

(3) Not discourage the use of gloves for phlebotomy; and

(4) Require that gloves be used for phlebotomy in the following circumstances:

(i) When the employee has cuts, scratches, or other breaks in his or her skin;

(ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(iii) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(4) *Housekeeping*. (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(i) Closable;

(ii) Puncture resistant;

(iii) Leakproof on sides and bottom; and

(iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(2) During use, containers for contaminated sharps shall be:

(i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(ii) Maintained upright throughout use; and

(iii) Replaced routinely and not be allowed to overfill.

(3) When moving containers of contaminated sharps from the area of use, the containers shall be:

(i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; and

(ii) Placed in a secondary container if leakage is possible. The second container shall be:

(A) Closable;

(B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

(C) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment. (1) Regulated waste shall be placed in containers which are:

(i) Closable;

(ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping;

(iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(2) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

(i) Closable;

(ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping;

(iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(B) The employer shall ensure that the employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

(C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) *HIV and HBV Research Laboratories and Production Facilities*. (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(ii) Special practices.

(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled, or color-coded container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(i) of this standard.

(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(H) Before disposal, all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment equipment. (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors, and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) *Training Requirements*. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) *Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up*—(1) *General*. (i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) *Hepatitis B Vaccination*. (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) *Post-Exposure Evaluation and Follow-up*. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status:

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service,

(v) Counseling, and

(vi) Evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional*. (i) The employer shall ensure that the healthcare professional responsible for the employee's hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(5) *Healthcare Professional's Written Opinion*. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for hepatitis B vaccination shall be limited to whether hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials, which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) *Medical recordkeeping*. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) *Communication of Hazards to Employees*—(1) *Labels and Signs*. (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious material, and other containers used to store, transport, or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F), and (G).

(B) Labels required by this section shall include the following legend:

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by this standard shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment, or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

[Name of the Infectious Agent]

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

(2) *Information and Training*. (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) Within 90 days after the effective date of the standard; and

(C) at least annually thereafter.

(iii) For employees who have received training on blood-borne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of this standard which were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) An explanation of the signs and labels and/or color-coding required by paragraph (g)(1); and

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) *Recordkeeping*—(1) *Medical Records*. (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) A copy of the employee's hepatitis B vaccination status including the dates of all of the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3).

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B), (C) and (D).

(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(A) Kept confidential; and

(B) Are not disclosed or reported without the employee's express written consent to any persons within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records*. (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) *Availability*. (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) *Transfer of Records*. (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so within that three month period.

(5) *Sharps injury log*. (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(A) The type and brand of device involved in the incident,

(B) The department or work area where the exposure incident occurred, and

(C) An explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(i) *Dates*—(1) *Effective Date*. The standard shall become effective on 6 March 1992.

(2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before 5 May 1992.

(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before 4 June 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect 6 July 1992.

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Annex G
(informative)

Bibliography

ALVARADO CJ, and REICHELDERFER M. APIC guideline for infection prevention and control in flexible endoscopy. *Amer J Infect Control*, 2000, vol. 28, no. 2, pp. 138–155.

AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS. *2002 TLVs® and BEIs®*. Cincinnati: ACGIH, 2001.

AMERICAN INSTITUTE OF ARCHITECTS ACADEMY OF ARCHITECTURE FOR HEALTH. *Guidelines for design and construction of hospital and health care facilities*. Washington (DC): American Institute of Architects Press, 2001.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Emergency eyewash and shower equipment*. ANSI Z358.1:1998. New York: ANSI, 1998.

AMERICAN SOCIETY FOR HEALTHCARE CENTRAL SERVICE PROFESSIONALS. *Training manual for central service technicians*. Chicago: American Hospital Association, 2001.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Reuse of hemodialyzer blood tubing*. AAMI TIR6:1989. Arlington (VA): AAMI, 1989.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hemodialysis systems*. ANSI/AAMI RD5:1992. Arlington (VA): AAMI, 1992a.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Table-top dry (heated air) sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST40:1992. Arlington (VA): AAMI, 1992b.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe handling of biologically contaminated medical devices in nonclinical and clinical settings*. AAMI TIR10:1993. Arlington (VA): AAMI, 1993. AAMI Technical Information Report.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers*. AAMI TIR12:1994. Arlington (VA): AAMI, 1994a. AAMI Technical Information Report.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Selection of surgical gowns and drapes in health care facilities*. AAMI TIR11:1994. Arlington (VA): AAMI, 1994b. AAMI Technical Information Report.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Flash sterilization: Steam sterilization of patient care items for immediate use*. 2nd ed. ANSI/AAMI ST37:1996. Arlington (VA): AAMI, 1996. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care, medical and dental facilities*. 2nd ed. ANSI/AAMI ST42:1998. Arlington (VA): AAMI, 1998. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*. ANSI/AAMI ST41:1999. Arlington (VA): AAMI, 1999. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Chemical sterilants and high-level disinfectants: A guide to selection and use*. AAMI TIR7:1999. Arlington (VA): AAMI, 2000a. AAMI Technical Information Report.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Processing of reusable surgical textiles for use in health care facilities*. ANSI/AAMI ST65:2000. Arlington (VA): AAMI, 2000b. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Reuse of hemodialyzers*. ANSI/AAMI RD47:2002. Arlington (VA): AAMI, 2002a. American National Standard.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Steam sterilization and sterility assurance in health care facilities*. 4th ed. ANSI/AAMI ST46:2002. Arlington (VA): AAMI, 2002b. American National Standard.

ASSOCIATION OF OFFICIAL ANALYTICAL CHEMISTS. *Official methods of analysis of AOAC International*. 17th ed. Washington (DC): AOAC, 2000.

ASSOCIATION OF PERIOPERATIVE REGISTERED NURSES. Recommended practices for the care and cleaning of surgical instruments and powered equipment. November 1996 Revision. In: *AORN Standards, Recommended Practices & Guidelines*. Denver: AORN, 2002a.

ASSOCIATION OF PERIOPERATIVE REGISTERED NURSES. Recommended practices for environmental cleaning in the surgical practice setting. June 1996 Revision. In: *AORN Standards, Recommended Practices & Guidelines*. Denver: AORN, 2002b.

AYCLIFFE GAJ. Equipment-related infection risks. *J Hosp Infec*, 1988, vol. 11 (Suppl. A), pp. 279–284.

BENNETT JV, and BRACHMAN PS, eds. *Hospital infections*. Boston/Toronto: Little, Brown and Company, 1986.

BLOCK SS. *Disinfection, sterilization, and preservation*. 3rd ed. Philadelphia: Lea and Febiger, 1983.

BLOCK SS. *Disinfection, sterilization, and preservation*. 4th ed. Philadelphia: Lea and Febiger, 1991.

BLOCK SS. *Disinfection, sterilization, and preservation*. 5th ed. Philadelphia: Lippincott, Williams & Wilkins, 2001.

BRADLEY DW. Transmission, etiology, and pathogenesis of viral hepatitis non-A, non-B, in nonhuman primates. In: CHISARI F, ed. *Advances in hepatitis research*. New York: Masson Publishing, USA, Inc., 1984, pp. 268–280.

CENTERS FOR DISEASE CONTROL. Recommendations for prevention of HIV transmission in healthcare settings. *Morbidity and Mortality Weekly Report* (MMWR), 21 August 1987, vol. 36, pp. 10S–11S.

CENTERS FOR DISEASE CONTROL. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *Morbidity and Mortality Weekly Report* (MMWR), 29 June 2001, vol. 50, no. RR-11.

COLE EC, RUTALA WA, NESSEN L, WANNAMAKER NS, and WEBER, DJ. Effects of methodology, dilution, and exposure time on the tuberculocidal activity of glutaraldehyde-based disinfectants. *Appl Envir Microbiol*, 1990, vol. 56, no. 6, pp. 11813–11817.

DANIELSON NE. *Ethylene oxide use in hospitals: A manual for health care personnel*. 3rd ed. Chicago: American Society for Healthcare Central Service Professionals of the American Hospital Association, 1998.

DEGROTT-KOSOLCHAROEN J, and JONES JM. Permeability of latex and vinyl gloves to water and blood. *Amer J Infec Control*, 1989, vol. 17, no. 4, pp. 196–201.

FAVERO M, and BOND W. Chemical disinfection of medical surgical material. In: BLOCK SS, ed. *Disinfection, sterilization, and preservation*. 4th ed. Philadelphia: Lea & Febiger, 1991, pp. 617–641.

FAVERO M, and BOND W. Chemical disinfection of medical surgical material. In: BLOCK SS, ed. *Disinfection, sterilization, and preservation*. 5th ed. Philadelphia: Lippincott, Williams & Wilkins, 2001, pp. 881–917.

GARCIA R. Personal communication. 2001.

GARNER JS, and FAVERO MS. *Guideline for handwashing and hospital environmental control*, 1985. Atlanta: Centers for Disease Control, 1985.

GRAHAM GS. Decontamination: A microbiologist's perspective. *J Healthcare Matl Mgmt*, 1988, vol. 6, no. 1, pp. 36–41.

HEALTHCARE INFECTION CONTROL PRACTICE ADVISORY COMMITTEE (HICPAC). Guideline for isolation precautions in hospitals. *Amer J Infec Control*, 1996, vol. 24, pp. 24–52.

HO DD, MOUDGIL T, and ALAM M. Quantitation of human immunodeficiency virus type 1 in the blood of infected persons. *N Eng J Med*, December 1989, vol. 321, no. 24, pp. 1621–1625.

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS. *Comprehensive accreditation manual for hospitals: The official handbook* (CAMH). Chicago: JCAHO, 2000.

JORDAN SLP. The correct use of glutaraldehyde in the healthcare environment. *Gastroenterology Nursing*, 1995, vol. 18, pp. 142–145.

KRIZEK TJ, and ROBSON MC. Evolution of quantitative bacteriology in wound management. *Amer J Surg*, 1975, vol. 130, pp. 579–584.

LANPHEAR BP. Trends and patterns in the transmission of bloodborne pathogens to health care workers. *Epidemiologic Reviews*, 1994, vol. 16, no. 2, pp. 437–447.

MALKIN J. *Medical and dental space planning for the 1990s*. New York: Van Nostrand Rheinhold, 1989.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Air contaminants. *Code of Federal Regulations*, Title 29, Part 1910.1000.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Eye and face protection standard. *Code of Federal Regulations*, Title 29, Part 1910.133.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Hazard communication standard. *Code of Federal Regulations*, Title 29, Part 1910.1200.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Medical and first aid standard. *Code of Federal Regulations*, Title 29, Part 1910.151.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Occupational exposure to blood-borne pathogens. *Code of Federal Regulations*, Title 29, Part 1910.1030.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Occupational exposure to ethylene oxide. *Code of Federal Regulations*, Title 29, Part 1910.1047.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION. Occupational exposure to formaldehyde. *Code of Federal Regulations*, Title 29, Part 1910.1048.

PERKINS JJ. *Principles and methods of sterilization in health sciences*. 2nd ed. Springfield (IL): Charles C Thomas, 1969.

PFLUG IJ, and SCHMIDT CF. Thermal destruction of microorganisms. In: BLOCK SS, ed. *Disinfection, sterilization, and preservation*. 2nd ed. Philadelphia: Lea & Febiger, 1968.

REA MS, ed. *Lighting handbook: Reference and application*. 8th ed. New York: Illuminating Engineering Society of North America, 1993. (Reprinted 1995. Most corrections that were submitted by the IESNA by August 1, 1994, were included in this printing.)

RUSSELL AD. Bacterial spores and chemical sporicidal agents. *Clin Microbiol Reviews*, 1990, vol. 3, no. 2, pp. 99–119.

RUTALA WA. Disinfection, sterilization and waste disposal. In: WENZEL RP, ed. *Prevention and control of nosocomial infections*. Baltimore: Williams and Wilkins, 1987.

RUTALA WA. APIC guideline for selection and use of disinfectants. *Amer J Infec Control*, 1996, vol. 24, pp. 313–342.

RUTALA WA, CLONTZ EP, WEBER DJ, and HOFFMAN KK. Disinfection practices for endoscopes and other semicritical items. *Infect Control and Hosp Epidemiol*, 1991b, vol. 12, pp. 282–288.

RUTALA WA, COLE EC, WANNAMAKER NS, and WEBER DJ. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Amer J Med*, 1991a, vol. 91, no. 3B, pp. 267S–271S.

RUTALA WA, STIEGEL MM, SARUBBI FA, and WEBER DJ. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. *Infect Control and Hosp Epidemiol*, 1997, vol. 18, pp. 417–421.

RUTALA WA, and WEBER DJ. Creutzfeldt-Jakob Disease: Recommendations for disinfection and sterilization. *Clin Infect Diseases*, 2001, vol. 32, pp. 1348–1356.

SHIKATA T, et al. Hepatitis B antigen and infectivity of hepatitis B virus. *J Infec Diseases*, 1977, vol. 136, no. 4, pp. 571–576.

SOULE BM, ed. *The APIC curriculum for infection control practice*. Vol. 1. Washington (DC): Association for Professionals in Infection Control and Epidemiology, 1983.

SPAULDING EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res*, 1972, vol. 9, pp. 5–31.

UNITED STATES PHARMACOPEIAL CONVENTION. *The United States Pharmacopeia*. Vol. 24. Rockville (MD): USP, 2000.

U.S. DEPARTMENT OF TRANSPORTATION. Hazardous material regulations. *Code of Federal Regulations*, Title 49, parts 170 through 178.

U.S. FOOD AND DRUG ADMINISTRATION. General hospital and personal use devices; Classification regulations. *Federal Register*, October 21, 1980, vol. 45, pp. 69678–69737.

U.S. FOOD AND DRUG ADMINISTRATION. *Guidance on premarket notification [510(k)] submissions for sterilizers intended for use in health care facilities*. Rockville (MD): FDA, March 1993a.

U.S. FOOD AND DRUG ADMINISTRATION. *Medical glove guidance manual*. 64 FR 41744. Rockville (MD): FDA, July 30, 1993b. Draft FDA Guidance Document.

U.S. FOOD AND DRUG ADMINISTRATION. *Labeling reusable medical devices in healthcare facilities: FDA reviewer guidance*. Rockville (MD): FDA, April 1996.

U.S. FOOD AND DRUG ADMINISTRATION. Medical devices; Exemptions from premarket notification and reserve devices; Class I. *Federal Register*, February 2, 1998a, vol. 63, pp. 5387–5393.

U.S. FOOD AND DRUG ADMINISTRATION. Medical devices; Exemptions from premarket notification; Class II devices. *Federal Register*, January 21, 1998b, vol. 63, pp. 3142–3145.

U.S. FOOD AND DRUG ADMINISTRATION. FDA Modernization Act of 1997: Guidance for the recognition and use of consensus standards; Availability. *Federal Register*, February 25, 1998c, vol. 63, pp. 9561–9569.

U.S. FOOD AND DRUG ADMINISTRATION. FDA Modernization Act of 1997: Modifications to the list of recognized standards; Availability; Withdrawal of draft guidance “Use of IEC 60601 standards; Medical electrical equipment.” *Federal Register*, October 16, 1998d, vol. 63, pp. 55617–55630.

U.S. FOOD AND DRUG ADMINISTRATION. *Guidance for industry and FDA reviewers: Content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants*. Rockville (MD): FDA, January 3, 2000a.

U.S. FOOD AND DRUG ADMINISTRATION. General hospital and personal use devices: Classification of liquid chemical sterilants/high level disinfectants and general purpose disinfectants. *Federal Register*, June 8, 2000b, vol. 65, no. 111, pp. 36324–36326.

U.S. FOOD AND DRUG ADMINISTRATION. Labeling. *Code of Federal Regulations*, Title 21, Part 801.

U.S. FOOD AND DRUG ADMINISTRATION. Medical device reporting. *Code of Federal Regulations*, Title 21, Part 803.

U.S. FOOD AND DRUG ADMINISTRATION. Medical devices; Adequate directions for use. *Code of Federal Regulations*, Title 21, Part 801.5.

U.S. FOOD AND DRUG ADMINISTRATION. Quality system regulation. *Code of Federal Regulations*, Title 21, Part 820.

U.S. POSTAL SERVICE. *Domestic Mail Manual*. Issue 52. Washington (DC); U.S. Government Printing Office, 1999.