

ELEMENT V

CREATION AND MAINTENANCE OF A SAFE ENVIRONMENT FOR PATIENT CARE IN ALL HEALTHCARE SETTINGS THROUGH APPLICATION OF INFECTION CONTROL PRINCIPLES AND PRACTICES FOR CLEANING, DISINFECTION, AND STERILIZATION

LEARNING OBJECTIVES

At the conclusion of course work or training on this element, the learner will be able to:

- Define cleaning, disinfection, and sterilization;
- Differentiate between non critical, semi critical, and critical medical devices;
- Describe the three levels of disinfection;
- Recognize the importance of the correct application of reprocessing methods for assuring the safety and integrity of patient care equipment in preventing transmission of bloodborne pathogens;
- Recognize the professional's responsibility for maintaining a safe patient care environment in all healthcare settings; and
- Recognize strategies for, and importance of, effective and appropriate pre-cleaning, chemical disinfection, and sterilization of instruments and medical devices aimed at preventing transmission of bloodborne pathogens.

DEFINITIONS

Contamination: The presence of microorganisms on an item or surface.

Cleaning: The process of removing all foreign material (i.e., dirt, body fluids, lubricants) from objects by using water and detergents or soaps and washing or scrubbing the object

Critical device: An item that enters sterile tissue or the vascular system. These must be sterile prior to contact with tissue.

Decontamination: 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.

Disinfection: The use of a chemical procedure that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects.

High level disinfection: Disinfection that kills all organisms, except high levels of bacterial spores, and is effected with a chemical germicide cleared for marketing as a sterilant by the U.S. Food and Drug Administration (FDA).

Intermediate level disinfection: Disinfection that kills mycobacteria, most viruses, and bacteria with a chemical germicide registered as a "tuberculocide" by the U.S. Environmental Protection Agency (EPA).

Low level disinfection: Disinfection that kills some viruses and bacteria with a

chemical germicide registered as a hospital disinfectant by the EPA.

Non critical device: An item that contacts intact skin but not mucous membranes. It requires low level disinfection.

Semi critical device: An item that comes in contact with mucous membranes or non intact skin and minimally requires high level disinfection.

Sterilization: The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

CONTENT OUTLINE

I. Universal principles

A. Instruments, medical devices and equipment should be managed and reprocessed according to recommended/appropriate methods regardless of a patient's diagnosis except for cases of suspected prion disease.

1. Special procedures are required for handling brain, spinal, or nerve tissue from patients with known or suspected prion disease (e.g., Creutzfeldt-Jakob disease [CJD]). Consultation with infection control experts prior to performing procedures on such patients is warranted.

B. Industry guidelines as well as equipment and chemical manufacturer recommendations should be used to develop and update reprocessing policies and procedures.

- C. Written instructions should be available for each instrument, medical device, and equipment reprocessed.

II. Potential for contamination is dependent upon

- A. Type of instrument, medical device, equipment, or environmental surface
 - 1. Potential for external contamination (e.g., presence of hinges, crevices).
 - 2. Potential for internal contamination (e.g., presence of lumens).
 - 3. Physical composition, design, or configuration of the instrument, medical device, equipment, or environmental surface.
- B. Frequency of hand contact with instrument medical device, equipment, or environmental surface.
- C. Potential for contamination with body substances or environmental sources of microorganisms.
- D. Level of contamination.
 - 1. Types of microorganisms
 - 2. Number of microorganisms
 - 3. Potential for cross-contamination

III. Steps of Reprocessing

- A. Pre-cleaning
 - 1. Removes soil, debris, lubricants from internal and external surfaces
 - 2. To be done as soon as possible after use
- B. Cleaning
 - 1. Manual (e.g., scrubbing with brushes)

2. Mechanical (e.g., automated washers)
 3. Appropriate use and reprocessing of cleaning equipment (e. g., do not reuse disposable cleaning equipment)
 4. Frequency of solution changes
- C. Disinfection- requires sufficient contact time with chemical solution
- D. Sterilization- requires sufficient exposure time to heat, chemicals, or gases

IV. Choice/Level of reprocessing sequence

- A. Based on intended use (see Definitions):
1. Critical instruments and medical devices require sterilization.
 2. Semi critical instruments and medical devices minimally require high level disinfection.
 3. Noncritical instruments and medical devices minimally require cleaning and low level disinfection.
- B. Based on manufacturer's recommendations
1. Compatibility among equipment components, materials, and chemicals used
 2. Equipment heat and pressure tolerance
 3. Time and temperature requirements for reprocessing

V. Effectiveness of reprocessing instruments, medical devices and equipment

- A. Cleaning prior to disinfection
- B. Disinfection
1. Selection and use of disinfectants
 - a. Surface products

- b. Immersion products
- 2. Presence of organic matter
- 3. Presence of biofilms
- 4. Monitoring
 - a. Activity and stability of disinfectant
 - b. Contact time with internal and external components
 - c. Record keeping/tracking of instrument usage and reprocessing
- 5. Post-disinfection handling and storage

C. Sterilization

- 1. Selection and use of methods
- 2. Monitoring
 - a. Biologic monitors
 - b. Process monitors (tape, indicator strips, etc.)
 - c. Physical monitors (pressure, temperature gauges)
 - d. Record keeping and recall/ tracking system for each sterilization processing batch/item
- 2. Post-sterilization handling, packaging and storage (event-related criteria)

VI. Recognizing potential sources of cross-contamination in the healthcare environment

- A. Surfaces or equipment which require cleaning between patient procedures/treatments
- B. Practices that contribute to hand contamination and the potential for cross-contamination

- C. Consequences of reuse of single-use/disposable instruments, medical devices or equipment

VII. Factors that have contributed to contamination in reported cases of disease transmission

- A. At any point in reprocessing or handling, breaks in infection control practices can compromise the integrity of instruments, medical devices or equipment.

- B. Specific factors

- 1. Failure to reprocess or dispose of items between patients
- 2. Inadequate cleaning
- 3. Inadequate disinfection or sterilization
- 4. Contamination of disinfectant or rinse solutions
- 5. Improper packaging, storage and handling
- 6. Inadequate/inaccurate record keeping of reprocessing requirements

VIII. Expectations of health professionals with respect to differing levels of disinfection and sterilization methods and agents based on the area of professional practice setting and scope of responsibilities

- A. Professionals who practice in settings where handling, cleaning, and reprocessing equipment, instruments or medical devices is performed elsewhere (e.g., in a

dedicated Sterile Processing Department):

- 1. Understand core concepts and principles
 - a. Standard and Universal Precautions (e.g., wearing of personal protective equipment)
 - b. Cleaning, disinfection, and sterilization described in Sections III and IV above

- c. Appropriate application of safe practices for handling instruments, medical devices and equipment in the area of professional practice.
- d. Designation and physical separation of patient care areas from cleaning and reprocessing areas is strongly recommended by NYSDOH

2. Verify with those responsible for reprocessing what steps are necessary prior to submission

- a. Pre-cleaning
- b. Soaking

B. Professionals who have primary or supervisory responsibilities for equipment , instruments or medical device reprocessing (e.g., Sterile Processing Department staff or clinics and physician practices where medical equipment is reprocessed on-site):

1. Understand core concepts and principles

- a. Standard and Universal Precautions
- b. Cleaning, disinfection, and sterilization described in Sections III and IV above
- c. Appropriate application of safe practices for handling instruments, medical devices, and equipment in the area of professional practice
- d. Designation and physical separation of patient care areas from cleaning and reprocessing areas is strongly recommended by NYSDOH

2. Determine appropriate reprocessing practices taking into consideration:

a. Selection of appropriate methods

i. Antimicrobial efficacy

ii. Time constraints and requirements for various methods

iii. Compatibility among equipment/materials

1. Corrosiveness

2. Penetrability

3. Leaching

4. Disintegration

5. Heat tolerance

6. Moisture sensitivity

iv. Toxicity

1. Occupational health risks

2. Environmental hazards

3. Abatement methods

4. Monitoring exposures

5. Potential for patient toxicity/allergy

v. Residual effect

1. Antibacterial residual

2. Patient toxicity/allergy.

vi. Ease of use

1. Need for specialized equipment

2. Special training requirements

- vii. Stability

1. Concentration

2. Potency

3. Efficacy of use

4. Effect of organic material

- viii. Odor

- ix. Cost

- x. Monitoring

1. Frequency

2. FDA regulations for reprocessing single use

devices (refer to the FDA web site at:

<http://www.fda.gov/cdrh/reprocessing/>