North Carolina SPICE Statewide Program for Infection Control & Epidemiology

Module F

PRINCIPLES OF DISINFECTION AND STERILIZATION IN THE OUTPATIENT DIALYSIS SETTING

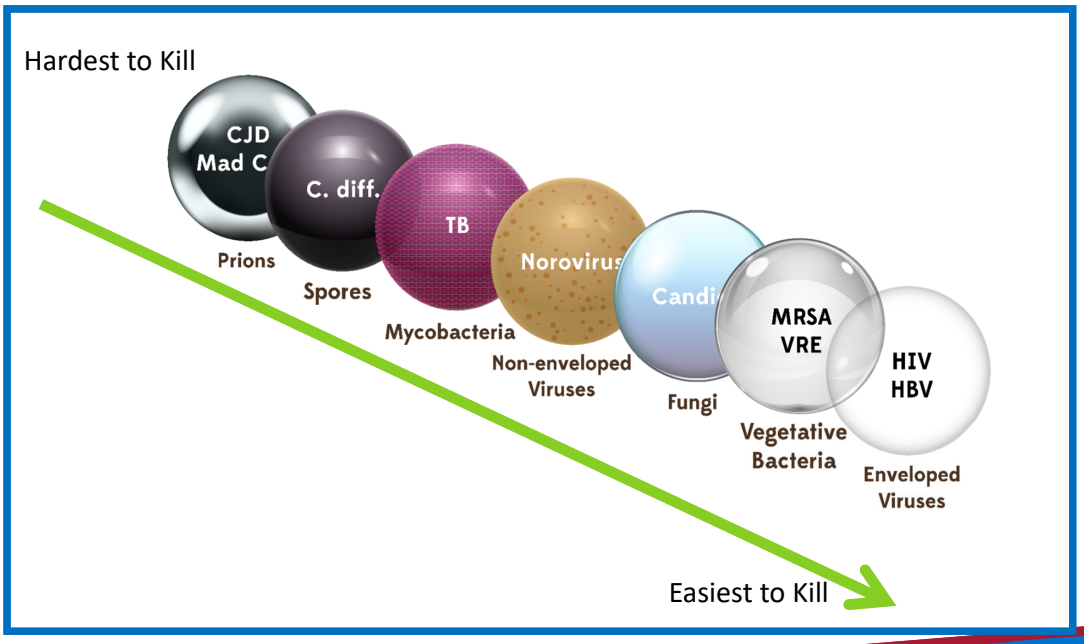
Statewide Program for Infection Control and Epidemiology (SPICE)

UNC School of Medicine

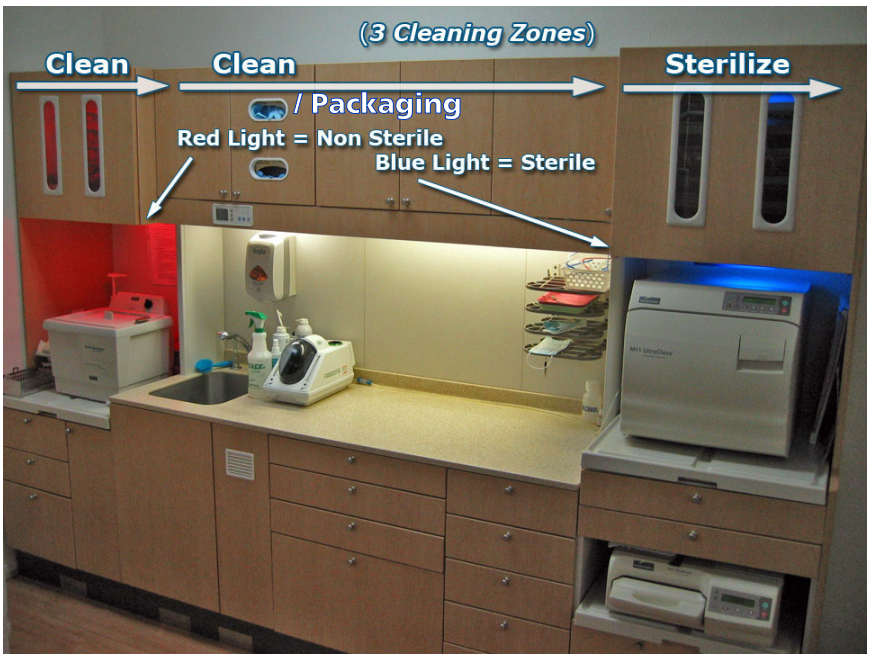
OBJECTIVES

- Describe the principles of disinfection and sterilization
- Provide an overview of current methods for disinfection and sterilization
- Discuss training and quality control methods and required documentation

PRINCIPLES



PRINCIPLES



PRINCIPLES

- Management of reusable contaminated items:
  - Handle as little as possible
  - Use appropriate PPE
  - Remove gross soil or debris at the point of use (gauze sponge moistened with water/disinfectant wipe for example)
  - Immediately contain and transport to the decontamination area or soiled utility room where cleaning procedures can be accomplished away from patient care

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PRINCIPLES

- Transport of contaminated items:
  - Must be contained. The type of container depends on the item being transported:
  - Puncture-resistant, leak-proof, closable containers must be used for devices with edges or points capable of penetrating container or skin
  - Must have a bio-hazard label or be red in color (never via gloved hands alone)
  - Items should be kept moist during transport by adding a towel moistened with water (not saline) or a foam, spray or gel product specifically intended for this use
  - Avoid transporting contaminated items in a liquid
- Reusable collection containers for holding contaminated items should be made of material that can be effectively decontaminated
- Use separate collection containers for contaminated versus re-processed or clean items

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PRINCIPLES

- Factors influencing the efficacy of disinfection and sterilization
  - How well the object is cleaned
  - Type and amount of material
  - Solution concentration
  - Exposure time
  - Design of object
  - Temperature and pH of disinfectant

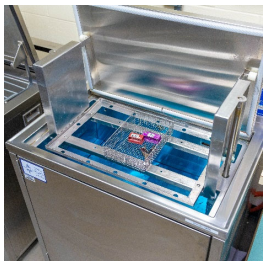
CLEANING INSTRUMENTS

MANUAL

- Medical equipment/devices MUST be pre-cleaned prior to high level disinfection or sterilization
- Contaminants such as dirt, blood or other body fluids, if present, can act as a barrier
- ALWAYS REMEMBER:
  - Do not use a high-level disinfection or sterilant solution to “hold” instrument
  - A fluid-resistant gown should be worn
  - Wear puncture-resistant heavy- duty utility gloves
  - Wear face protection (eyes and mouth) to protect against splashes

CLEANING INSTRUMENTS

AUTOMATED



Benefits:

Improve efficacy of cleaning process

Reduce handling of sharp instruments

Reduce risk of employee exposure

Automated cleaning equipment

Ultrasonic cleaner

Instrument washer

FDA regulated instrument washer

Follow manufacturer's recommendations:

Dilution

Temperature

Water hardness

Use

After cleaning, rinse with water

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KNOWLEDGE CHECK

Which of the following statements is true?

1. Manual cleaning of objects is safer than automated cleaning
2. ✓ e-cleaning is the most important factor in processing objects
3. Objects do not need to be pre-cleaned if they are going to be sterilized
4. Household dishwashers can be used for pre-cleaning of instruments.

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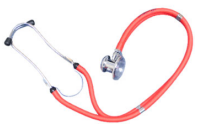
METHODS USED FOR DISINFECTION AND STERILIZATION

SPAULDING CLASSIFICATION

Spaulding Classification of Surfaces:

Critical – Objects which enter normally sterile tissue or the vascular system and require sterilization

Semi-critical – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores



Non-critical – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

PROCESSING CRITICAL INSTRUMENTS

- Critical Items:
  - Penetrate or enter normally sterile tissue or spaces, including the vascular system (Surgical instruments, cardiac catheters, IV devices, urinary catheters)
  - High risk of transmitting infection if handled improperly
  - Must be sterilized between uses or used as single-use disposable devices

Goal: Sterility = devoid of all microbial life

METHODS

- Four activities involved in the sterilization and disinfection of critical objects
  - Sterilization/Disinfection

  (Steam, dry heat, liquid chemical)
  - Monitoring
  - Packaging

  (Wrapping, record keeping, loading)
  - Storage

STERILIZATION

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Ozone
- Vaporized hydrogen peroxide
- Steam formaldehyde

● = *high temperature*

● = *low temperature*

STEAM STERILIZATION

- Advantages

- Non-toxic
- Cycle easy to control and monitor
- Inexpensive
- Rapidly microbicidal
- Rapid cycle time
- Least affected by organic/inorganic soils
- Penetrates medical packing, device lumens

STEAM STERILIZATION

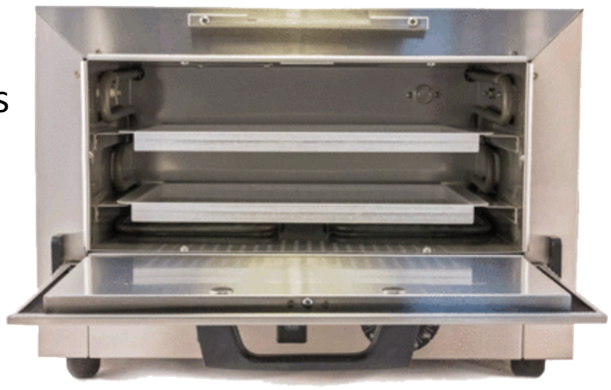
- Disadvantages
  - Deleterious for heat labile instruments
  - Inappropriate for heat-sensitive instruments
  - Inappropriate for moisture-sensitive instruments
    - Dulling
    - Rusting
  - Potential for burns

STEAM STERILIZATION

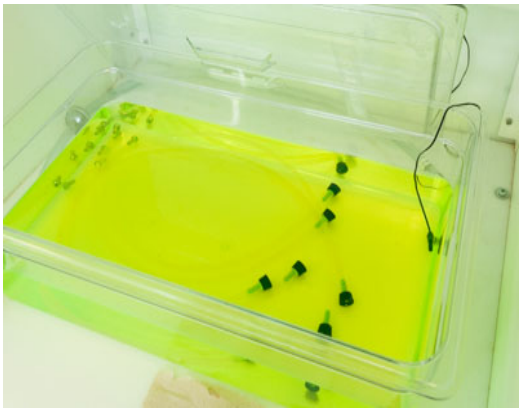
- Steam under pressure (autoclaving)
  - Gravity displacement:
    - Exposure: 30 minutes
    - Temperature: 121°C
  - Pre-vacuum:
    - Exposure: 4 minutes
    - Temperature: 132°C

DRY HEAT STERILIZATION

- Transfers heat energy from air inside the oven to the instruments
- Requires higher temperatures
- Good for items that are likely to dull or rust in the autoclave,
- Good for powders, cellulose and ink
- Packaging must be able to withstand high temperatures



LIQUID CHEMICAL STERILANTS/DISINFECTANTS



Liquid chemical sterilants/disinfectants

- Only for heat-sensitive critical and semi-critical devices
- Exposure can be harmful to providers and patients
- Can not be stored
- Heat tolerant or disposable alternatives are available

critical

STERILIZATION REVIEW

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Items immersed in chemo-sterilizer solutions should be used immediately

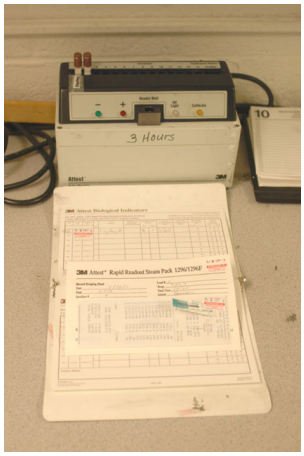
KNOWLEDGE CHECK

Patient care equipment and devices should be disinfected/sterilized based on:

1. Items intended use
2. What the item is going to come in contact with (mucous membranes or non-intact skin)
3. The number of patients you have scheduled for the day
4. What the physician tells you to do.

a. 1 and 4
b. 2 and 4
c. 1 and 2 ✓
d. 3 and 4

MONITORING



- The Joint Commission (TJC)
- Centers for Medicare and Medicaid Services (CMS)
- 10A NCAC 41.0206 (NC Rule .0206

STERILIZATION MONITORING

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters reached
- Biological - *Bacillus* spores that directly measure sterilization

MONITORING OF STERILIZERS

- Internal Chemical Indicator
  - Validates the sterilant penetrated the pack or tray
  - Advantage of the pack control monitor is that it is inside each pack in multiple locations
  - Detect local problem

BIOLOGICAL MONITORS

Steam - *Geobacillus stearothermophilus*

Dry heat - *B. atrophaeus (formerly B. subtilis)*

Ethylene oxide (ETO) - *B. atrophaeus*

MONITORING OF STERILIZERS

Following a single positive biological indicator from steam sterilization:

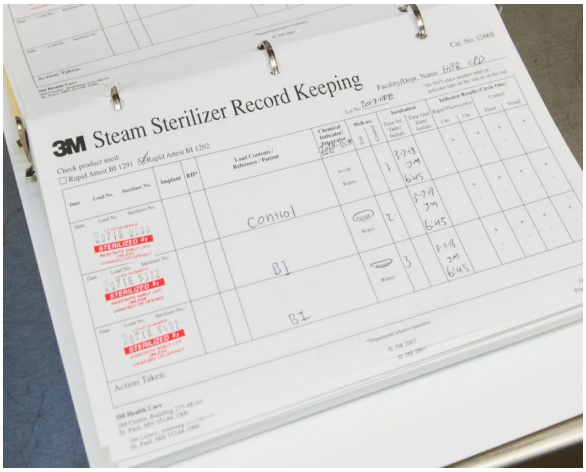
- Remove the sterilizer from service and review sterilizer instructions
- Retest the sterilizer
- If spore test negative, put the sterilizer back in service
- If the spore test is positive: do not use until it has been inspected; and recall (to the extent possible) all items processed since the last negative spore test; challenge in three consecutive empty sterilization cycles.

Single positive biological indicator (BI) from other than steam sterilization: treat as non-sterile all items back to last load tested with negative indicator

MONITORING REVIEW

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items
- Policy for management of positive BI indicator

Record-Keeping



Maintain sterilization records (physical, chemical and biological)

For each sterilization cycle record"

- the type of sterilizer and cycle used;
- the load identification number;
- the load contents,
- the exposure parameters (time and temperature);
- the operator's name or initials; and
- the results of physical, chemical, and biological monitoring.

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PACKAGING

Video Clip: To start the video click on the image.

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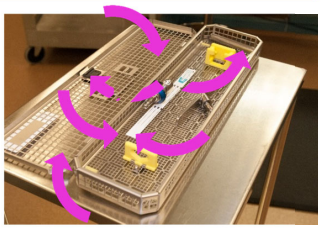
PACKAGING

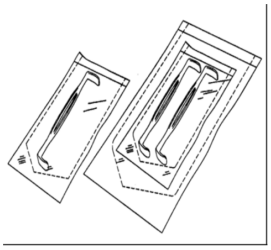
- Once cleaned, dried and inspected items, requiring sterilization must be:
  - Wrapped or place in rigid containers
  - Arranged in trays or baskets per Association of Medical Instrumentation (AAMI) guidelines (hinged instruments should be opened for example)
- Follow manufacturer's instructions for preparation
- Wrapping done to prevent gaps and tenting
- Wrapping material must:
  - Allow penetration of sterilant, be compatible with sterilizer, be puncture resistant, durable and have FDA clearance
- Choices in wrapping products include:
  - Peel packs, rigid containers, roll stock (self seal) and woven or nonwoven sterile wraps

LOADING

- Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant
- Peel packs and non-perforated containers should be placed on their edge



- Peel packs:
  - Be used, filled and opened according to the pouch manufacturer's instructions
  - Be of a size and strength to accommodate the item being packaged
  - Be closed so that all pouch seals are smooth (i.e., without folds, bubbles or wrinkles)
  - Be written only on the non-porous side of the pouch

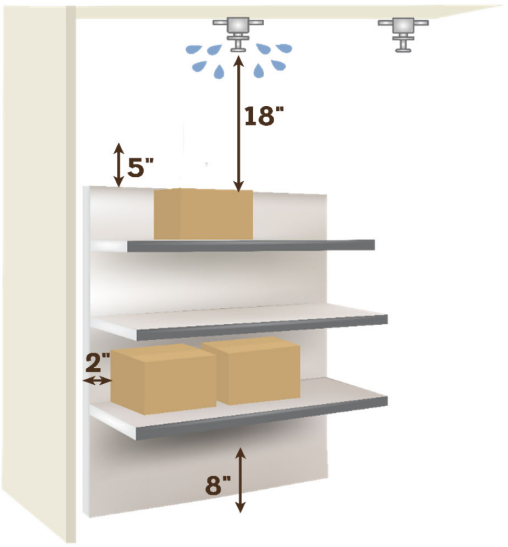


SUMMARY METHODS

- Steam is preferred for critical (and semi-critical) items not damaged by heat
- Always follow manufacturer's operating instructions
- Use an "FDA cleared" container, wrapping or packaging system that is compatible with the type of sterilization process used
- Do not overload the chamber

STORAGE OF STERILE ITEMS

- Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised.
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and if applicable the expiration date.



STORAGE OF STERILE ITEMS

- **Event-related** shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g. moisture).
- Packages should be evaluated before use for loss of integrity. Repack and reprocess if compromised.
- If **time related** storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack.

STORAGE

GENERAL GUIDELINES

- All patient care items must be stored at least 8" off the floor
- Open rack storage should have a bottom shelf (plexi-glass for example)
- Stored at least 18" below the ceiling or the sprinkler head (according to fire code)
- Stored at least 2" inches from outside wall
- Items should be stored in areas of limited traffic
- Stored in an area with controlled temperature and humidity
- Outside shipping containers and corrugated cartons should not be used as storage containers
- Items should not be stored under sinks or exposed water/sewer pipes
- Windowsills should be avoided
- Closed or covered cabinets are preferred

SPAULDING CLASSIFICATION

Spaulding Classification of Surfaces:

Critical – Objects which enter normally sterile tissue or the vascular system and require sterilization

Semi-critical – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores

Non-critical – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

SEMI-CRITICAL INSTRUMENTS

Semi-critical

- **Semi-Critical** Items:
  - Contact mucous membranes or non-intact skin (vaginal/rectal probes, vaginal specula, tonometers, respiratory therapy equipment etc.,)
  - Risk of transmitting infection if handled improperly
  - Must be high-level disinfected between uses or used as single-use disposable devices

Goal: High-level disinfection = free of all microorganisms except high numbers of bacterial spores

HIGH-LEVEL DISINFECTANTS

Semi-critical

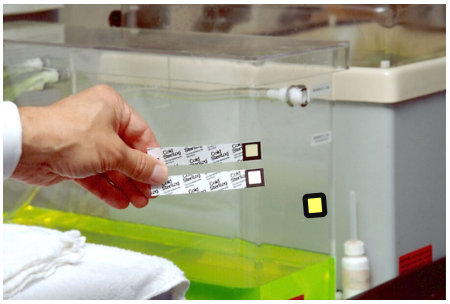
Germicide	Concentration
Glutaraldhyde (Cidex)	≥ 2.0%
Ortho-phthaladehyde (Cidex OPA)	0.55%
Hydrogen Peroxide* (Sporox)	7.5%
Hydrogen Peroxide and peracetic acid* (Peract)	1.0% / 0.08%
Hydrogen Peroxide and peracetic acid* (Endospore +)	7.5% / 0.23%
Hypochlorite (free chlorine)* (Sterilox ©)	650-675 ppm
Accelerated hydrogen peroxide (Resert XL)	2.0%
Peracetic Acid (Steris 20)	0.2%
Glutaraldehyde and Isopropanol (Aldahol III)	3.4% / 26%
Glutaraldehyde and phenol/phenate (Sporicidin)	1.21% / 1.93%

PROCESSING SEMI-CRITICAL INSTRUMENTS

Semi-critical

Methods for processing:

A common method used in outpatient facilities is immersion in either Glutaraldehyde (Cidex®) or Ortho-phthaladehyde (Cidex OPA®)



Manufacturer's instructions for dilution and quality control testing must be followed. Must use correct test strip for solution!

Semi-critical

- Submerge the test strip into the solution prior to each use to monitor minimum effective concentration (MEC)
- Remove excess by standing upright on paper towel
- Read results according to manufacturer's instructions *(recommended time period and change in color of the test strip)*
- Document findings

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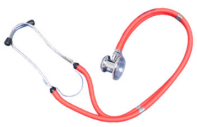

Non-critical – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

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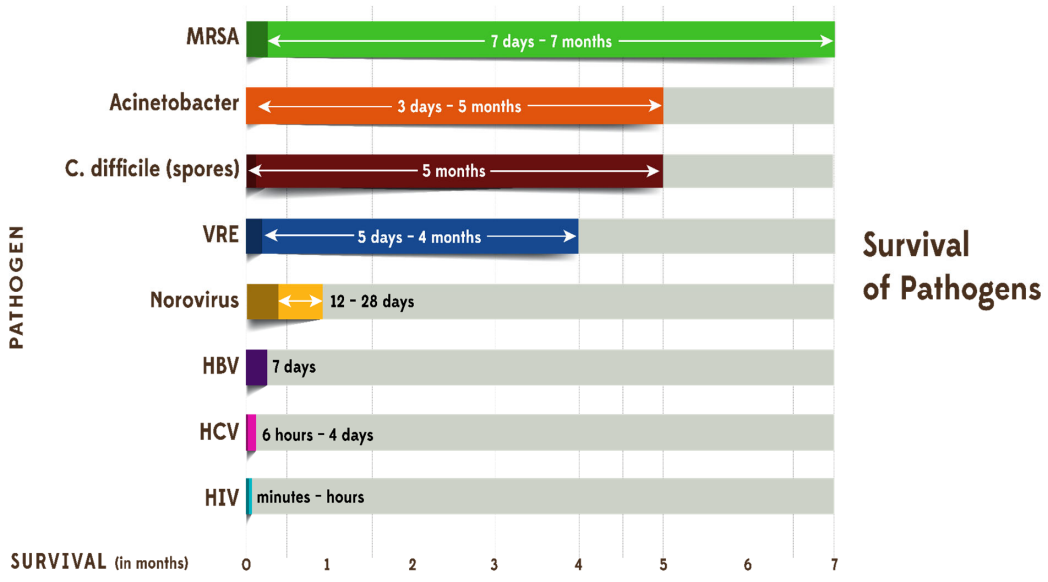
NON-CRITICAL INSTRUMENTS

Non-critical

- **Non-Critical** Items:
  - Objects that contact intact skin but not mucous membranes (BP cuffs, stethoscopes, bedrails, exam tables)
  - Minimal risk of transmitting infection if handled improperly
  - Must be low-level disinfected on a routine basis

ROLE OF THE ENVIRONMENT

Non-critical



LIQUID DISINFECTANTS

Non-critical

Disinfectant Agent	Use Concentration
Ethyl or isopropyl alcohol	70% - 90%
Chlorine (bleach)	100 ppm
Phenolic	UD
Iodophor	UD
Quaternary ammonium compound (QUAT)	UD
Improved/Accelerated hydrogen peroxide	0.5%, 1.4%

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PROPERTIES OF AN IDEAL DISINFECTANT

Non-critical

- Broad Spectrum
- Fast Acting
- Non-toxic
- Surface Compatibility
- Easy to Use
- Acceptable odor
- Economical

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OTHER ENVIRONMENTAL ISSUES

OSHA

Blood and Body Fluid Spills

- Promptly clean and decontaminate
- Use appropriate PPE
- Clean spills with dilute bleach solution (1:10 or 1:100) or an EPA-registered hospital disinfectant with a TB or HIV/HBV kill claim.

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KNOWLEDGE CHECK

Contaminated reusable items should be:

1. Handled as little as possible
2. Placed in a bio-hazard labeled container and left in room until end of work day
3. Pre-cleaned in sink in the exam room
4. Transported immediately after use and not left in the patient care area

Select correct one

a. 1 and 3

b. 3 and 4

✓ c. 1 and 4

d. 1, 2, 3, 4

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TRAINING AND QUALITY CONTROL

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency:
  - Staff receive hands-on training
  - Work with supervision until competency is documented
  - Competency testing should be conducted at commencement of employment and no less than annually
  - Training and competencies should be documented

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TRAINING AND QUALITY CONTROL

- Conduct infection control rounds no less than annually and more often if high risk area (GI clinic, Urology, Endoscopy)
- Ensure all products used for disinfection and/or sterilization have been approved by infection prevention
- Follow manufacturer instructions for use (IFUs)for preparation and packing of items

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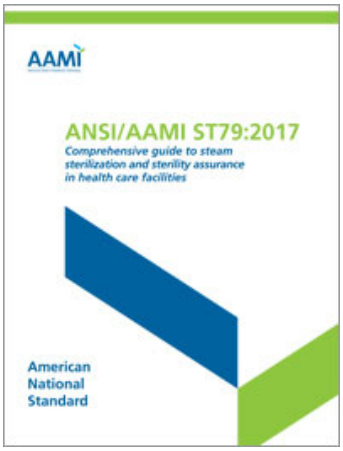
ADDITIONAL RESOURCES



Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

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QUESTIONS?

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