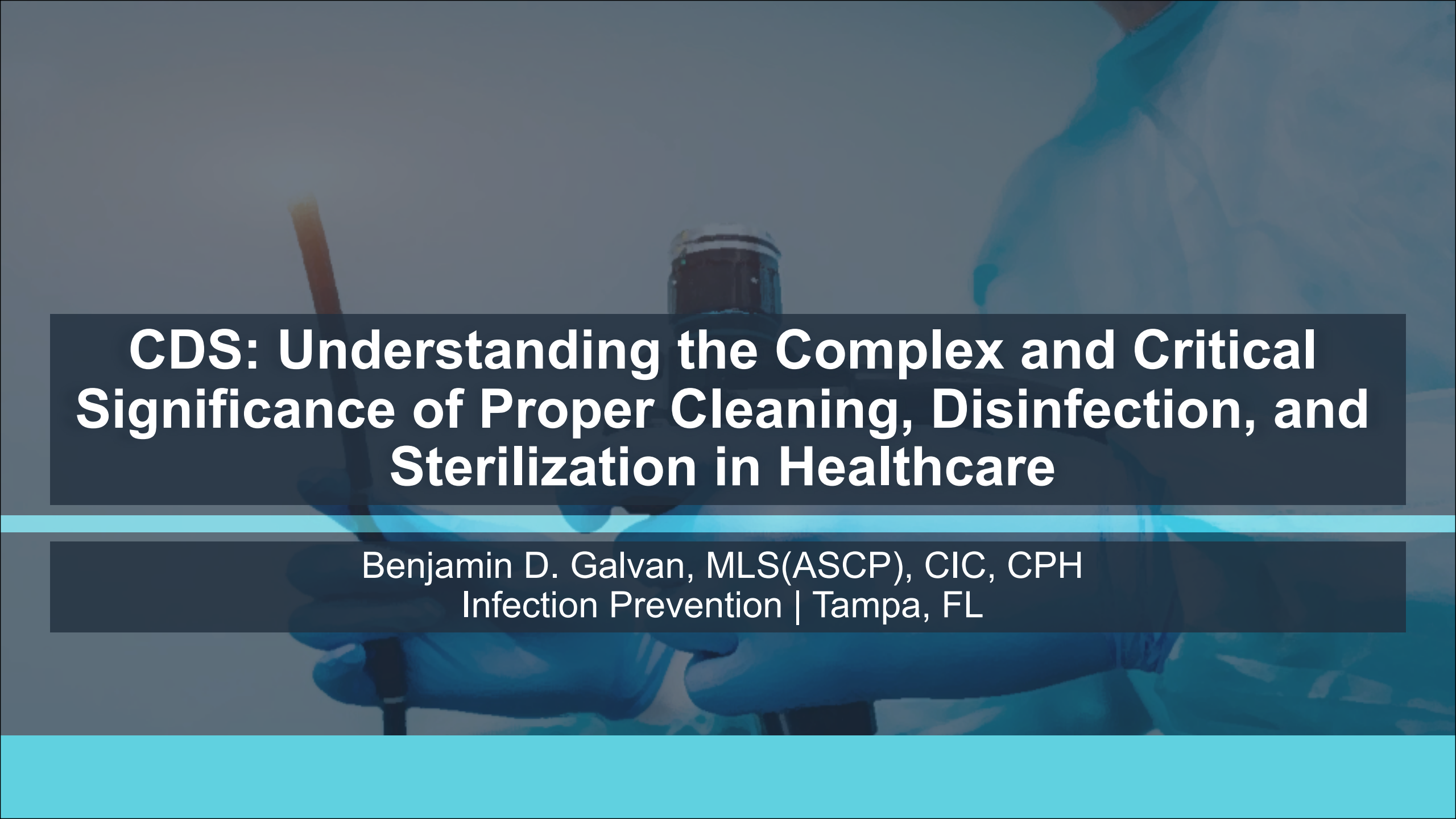


CDS: Understanding the Complex and Critical Significance of Proper Cleaning, Disinfection, and Sterilization in Healthcare

Benjamin D. Galvan, MLS(ASCP), CIC, CPH
Infection Prevention | Tampa, FL

Nothing to Disclose

Disclaimer: The appearance of any product or brand names in this webinar is for educational purposes only and is not meant to serve as an official endorsement by myself or the facility for which I represent. Any opinions expressed are that of my own.

Learning Objectives

1. Recognize the differences between cleaning, disinfection and sterilization in healthcare.

2. Describe the steps of reprocessing reusable medical equipment and the quality control associated with these practices

3. Review the potential safety issues that can occur when these processes fail and how to prevent them

History of CDS

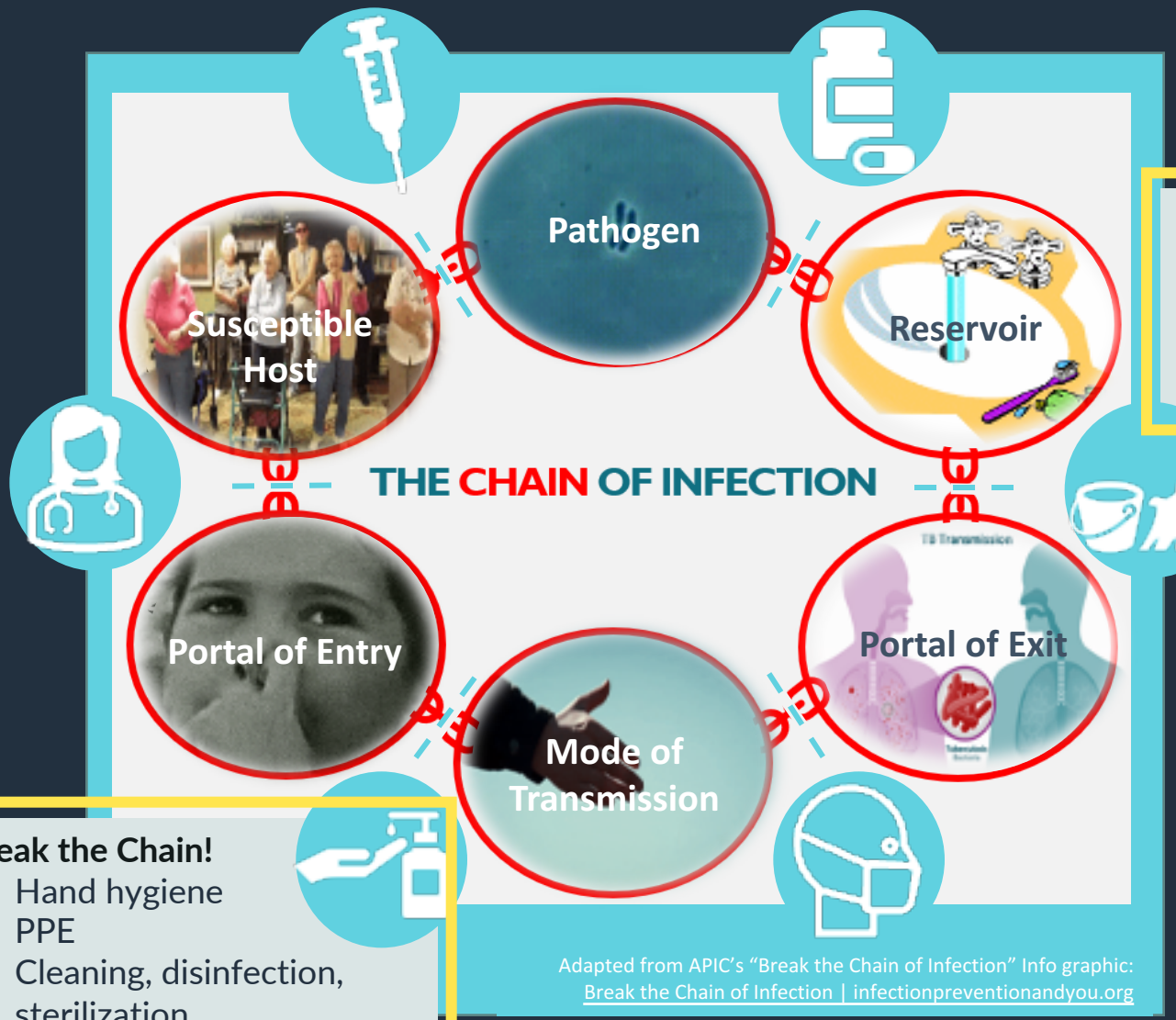
Brief History of CDS

- Little scientific knowledge of disinfection existed prior to the 19th century as there was very little understanding of the role of microbes in causing disease though there was suspicion that disease was cause by something harmful[1]
- Some of the first known “disinfectants” were sulfur, mercury, copper, alkalis, acids, heat, and fumigation – the idea being if you can see the chemical working or reacting (smoke, fire, bubbling), then it was effective[1]
  - 5000 BC – Chlorine compounds were used by the ancient Egyptians to whiten linens[2]
  - 1847 – **Ignaz Semmelweis** used chlorine solutions as hand disinfectants to reduce puerperal or “childbed” fever rates[2]
  - 1862 – **Louis Pasteur** proved that bacteria only evolve from existing bacterial cells and pioneered the development of disinfection, sterilization, and pasteurization practices[3]
  - 1865 to 1880 – **Joseph Lister** used phenolic agents in his work on surgical antisepsis, also used carbolic acid as an agent of choice in research related to sterilizing surgical instruments and wound cleansing[3]
  - 1905 – **Carl Flügge** introduced the distinction between hygienic and surgical hand “disinfection” [3]
  - 1916 – Quaternary ammonium compounds (QAC) discovered by the Rockefeller institute, with the first QAC being benzalkonium chloride (BZK). BZK served as an alternative to carbolic acid for skin antisepsis which led to investigative use as a surface disinfectant
  - And so on!
- Much scientific advancement has happened that has led to the development of the chemicals we recognize today

Article photo: 1856 advertisement for Dr. Christie's Ague Balsam - "a sure remedy for ague, fever and all bilious diseases"

[1] https://www.sterifre.com/resources/a-glance-back-at-the-history-of-disinfection
[2] https://pdihc.com/blog/history-and-evolution-of-surface-disinfectants/
[3] https://www.sterillium.info/en/why-hand-hygiene-programmes/the-history-of-hand-disinfection

Chain of Infection

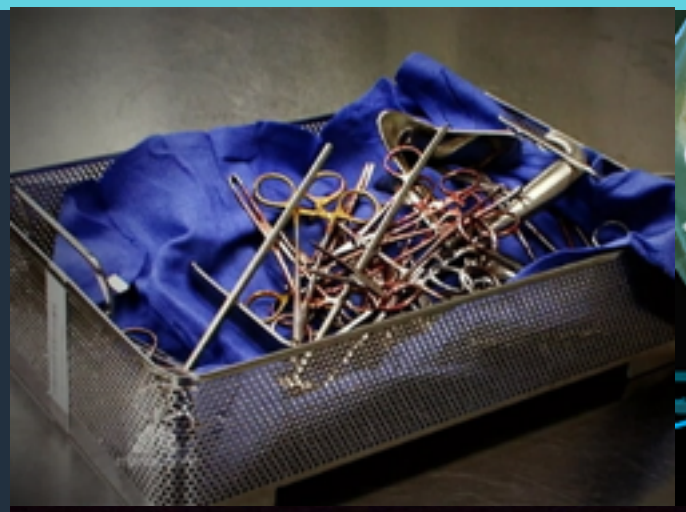


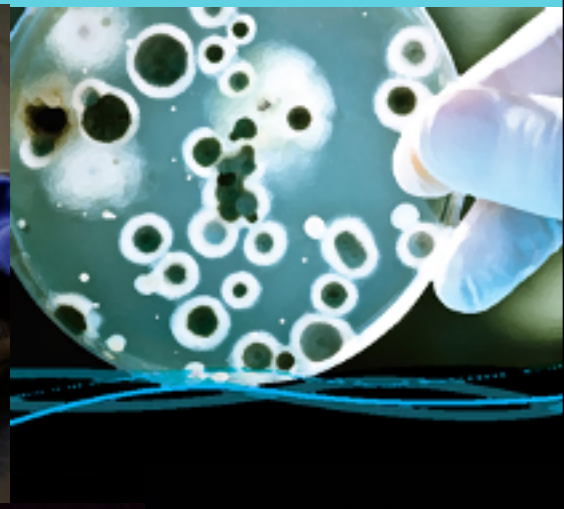
Break the Chain!
- Cleaning
- Disinfection
- Sterilization
- IP protocols

Break the Chain!
- Hand hygiene
- PPE
- Cleaning, disinfection, sterilization

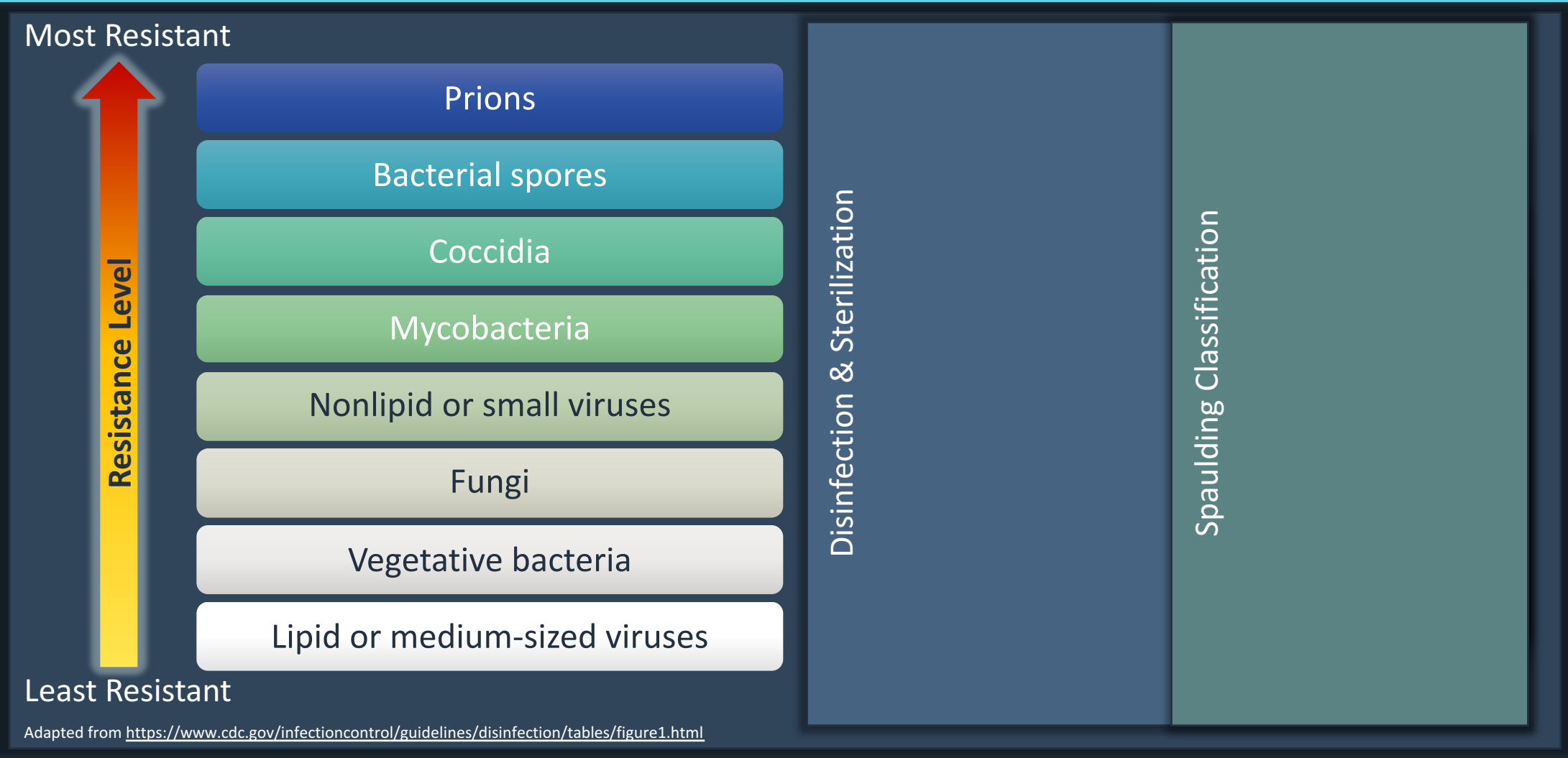
Soil vs Bioburden vs Biofilm

- *Soil* is the presence of organic material on a used device or instrument
  - Blood, Sputum, Stool
- *Bioburden* is the number of microbial organisms (e.g., bacteria) present on a surface
- *Biofilm* is the presence of a sticky, extracellular matrix formed by bacteria that protects them from physical removal, chemical disinfection, and antibiotic treatment.





Pathogen Survival



Adapted from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/figure1.html

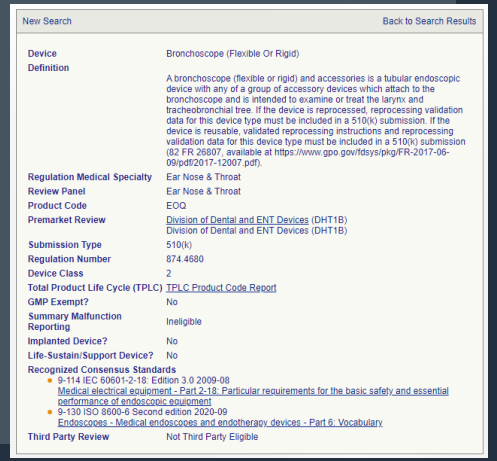
Regulation (EPA vs FDA)

Environmental Protection Agency (EPA)

- Writes rules and regulations regarding Environmental cleaners and disinfectants
- Considered pesticides
  - *"Any substance or formula intended for preventing, destroying, repelling or mitigating any pest…" – like bacteria*
  - Antimicrobial pesticides specifically
- EPA-Registered Disinfectants
  - Requires review of data for kill claims

Food and Drug Administration (FDA)

- Regulates chemicals and processes used for reprocessing medical equipment
  - Code of Federal Regulations (CFR)
  - Parts 800 – 1299
- Device recalls
- Event reporting
- Product Classification



New Search | Back to Search Results

Device	Bronchoscope (Flexible Or Rigid)
Definition	A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. If the device is reprocessed, reprocessing validation data for this device type must be included in a 510(k) submission. If the device is reusable, validated reprocessing instructions and reprocessing validation data for this device type must be included in a 510(k) submission (82 FR 26807, available at https://www.gpo.gov/fdsys/pkg/FR-2017-06-09/pdf/2017-12007.pdf).
Regulation Medical Specialty	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Product Code	EOQ
Premarket Review	Division of Dental and ENT Devices (DHT1B) Division of Dental and ENT Devices (DHT1B)
Submission Type	510(k)
Regulation Number	874.4680
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standards	9-114 IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment 9-130 ISO 8600-6 Second edition 2020-09 Endoscopes - Medical endoscopes and endotherapy devices - Part 6: Vocabulary
Third Party Review	Not Third Party Eligible

What is Cleaning, Disinfection, and Sterilization?

What it isn’t

- Cleaners, disinfectants and sterilants should not be used on living tissue (i.e., patients)
  - Some chemicals break down organic matter (enzymatics)
  - Chemicals are toxic, carcinogenic, malodorous, etc.
- Skin antiseptics
  - *Define*: Antimicrobial substances applied to living tissue for the purpose of reducing the number of bacteria and other microbes present on the skin
  - Examples:
    - Alcohol-based hand sanitizer
    - Chlorhexidine
    - Certain formulations of Iodophors (e.g., povidone iodine used for MRSA decolonization)
    - Mupirocin (Abx for nasal decolonization)

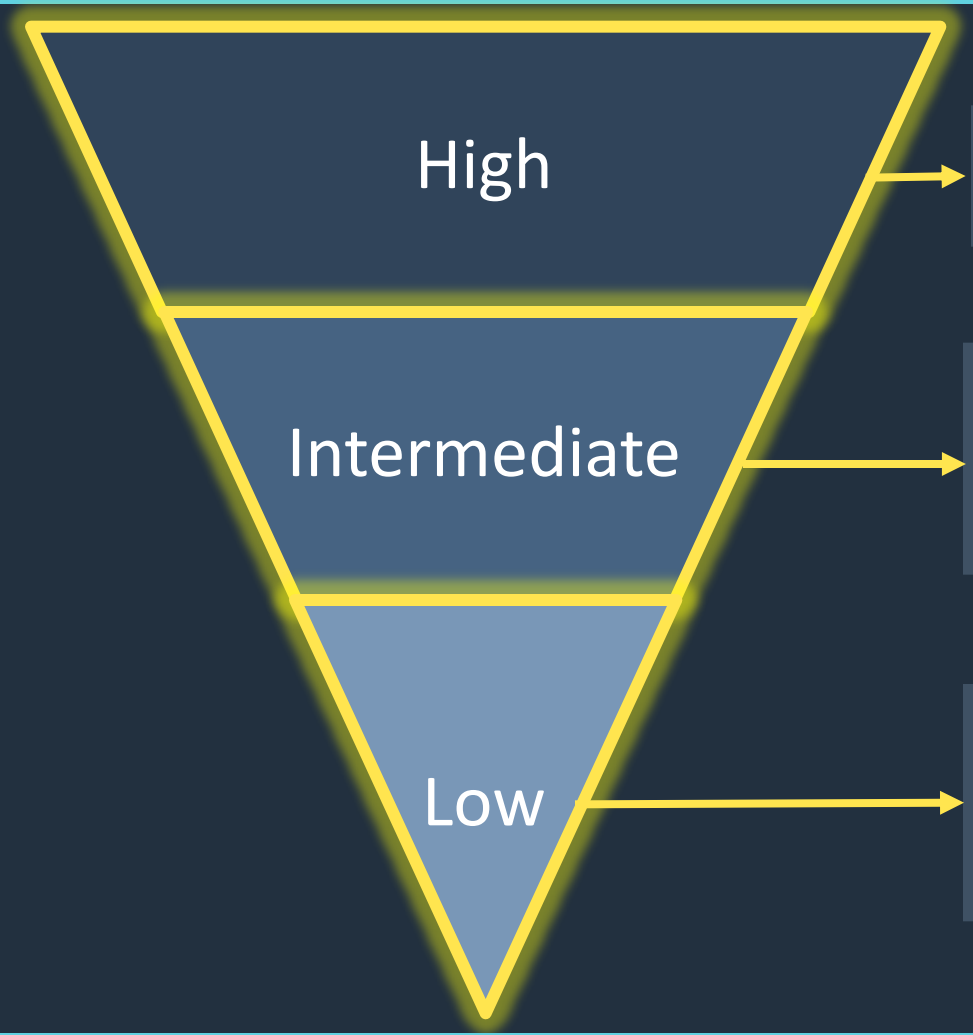
Cleaning

- *Definition*: The mechanical or manual removal of foreign material (e.g., soil, organic debris) from objects or surfaces
- *Application*: environmental surfaces and medical devices and equipment
- Cleaning agents are called “Detergents”
  1. Surfactants – lower surface tension of water; surrounds, pulls, and dissolves soil from the surface
  2. Enzymatics – break down organic soil (e.g., Amylase, Lipase, Protease)
- NOT necessarily microbicidal
- Some disinfectant products (e.g., pre-saturated wipes) may also serve as cleaners when used as directed (i.e., wipe and then disinfect)
- 2 ways to clean:
  1. *Mechanical* cleaning: using ultrasonic cleaners or washer/disinfectors
  2. *Manual* cleaning components:
     - Friction (rubbing/scrubbing)
     - Fluidics (fluids under pressure)

Disinfection

- *Definition:* Process that eliminates many or all pathogens, except high numbers of bacterial spores*
  - **Exception is chemical sporicidal disinfecting agents (e.g., chlorine derivatives/bleach)*
- *Application*: environmental surfaces and medical devices
  - Horizontal surfaces, water lines, & HVAC systems
- Not all disinfectants are made equal
  - Categories of disinfectants (low, intermediate, high)
  - Mode of action – how the disinfectant kills or inhibits microorganisms
  - Kill claim – what microorganisms is it effective against
  - Dwell time – contact/wet time; how long the surface must remain wet to achieve the kill claim (may be different for different organisms)

Categories of Disinfection



Kill claim includes all microbial life *except high numbers of bacterial spores*; used for medical devices and accessories

Kills most vegetative bacteria, most viruses, most fungi, and most *mycobacteria*; not necessarily sporicidal but can be (e.g., chlorine compounds); used for environmental surfaces and certain reusable medical devices and equipment

Kills most vegetative bacteria, some fungi, and some viruses; not sporicidal or tuberculocidal; used for environmental surfaces and certain reusable medical devices and equipment

Common Types of Chemical Disinfectants

Alcohols

Commonly used for medication septums, blood culture vials, and IV injection ports

Chlorine:

Sporicidal (C.diff patient rooms); used for Blood spills as it kills blood-borne pathogens

Formaldehyde:

Anatomic Specimens in pathology labs

Glutaraldehyde:

Disinfection of Endoscopes, Endocavity US probes

Iodophors:

Antiseptic (lower concentration); hydrotherapy tanks

OPA:

Disinfection of Endoscopes, Endocavity US probes

Peracetic Acid:

Liquid Chemical Sterilization of scopes and other devices

Hydrogen Peroxide:

Inanimate horizontal surfaces, equipment, endoscopes, HLD and low-temp sterilization

Phenolics

Certain reusable devices and surfaces – NOT to be used around infants (hyperbilirubinemia)

Quats:

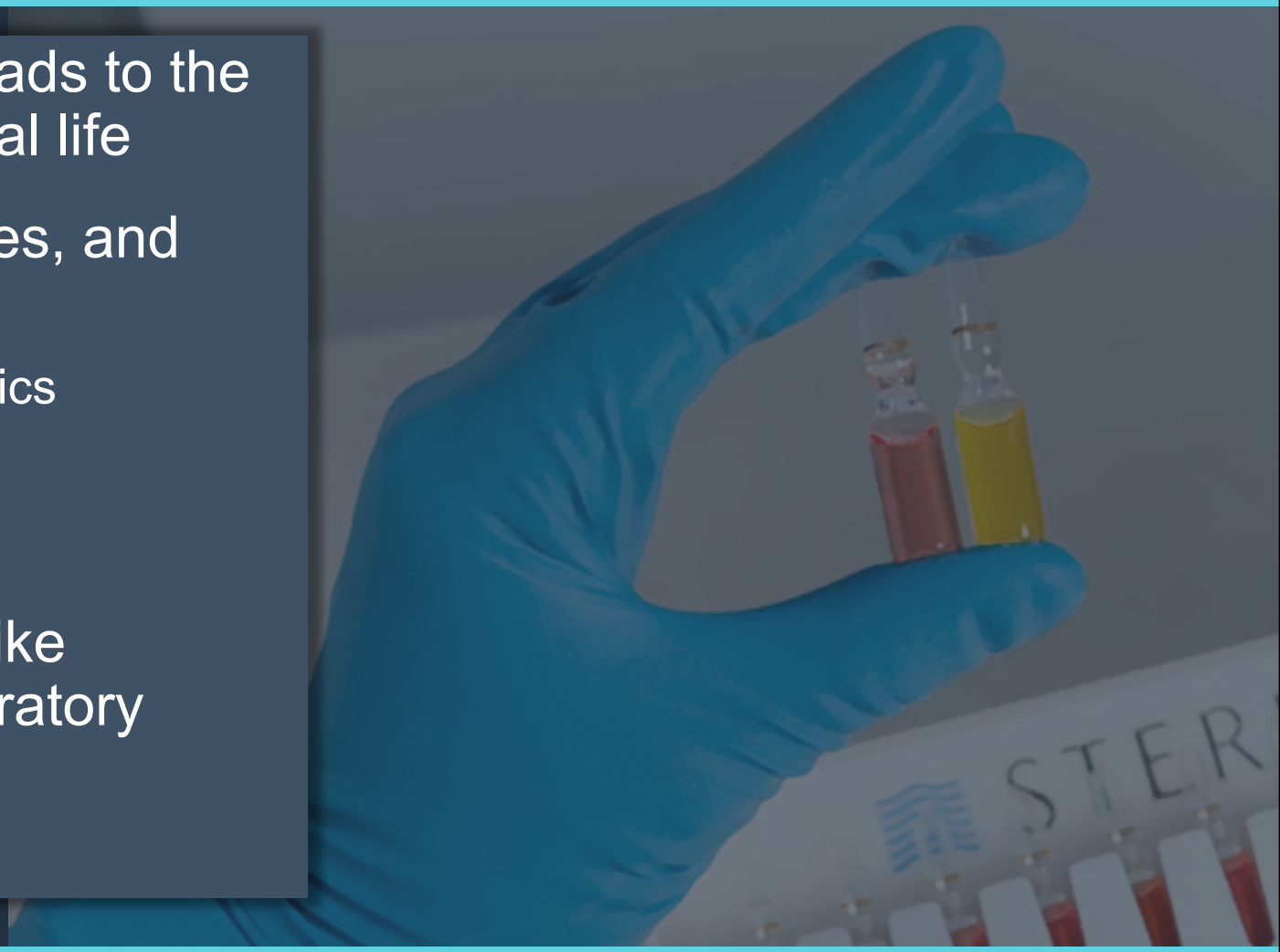
General hospital surfaces (e.g., floors, walls); certain reusable devices (BP cuff)

Disinfection Technologies

- Spray bottles
  - Pros and Cons (contamination, topping off, less control over spread, wiping can remove the product, etc.)
- Pre-moistened Wipes
  - Various formulations
  - Can control how much product you place on surface, allows for friction when wiping
- Concentrate
  - Requires careful tracking of dilution
- Foggers/Misters/Vaporizers/Electrostatic Sprayers
  - Hydrogen Peroxide and other disinfectants
  - May require certain types of PPE, prolonged aeration, etc.
- UV Germicidal Irradiation (UVGI)
  - Mobile “robots” and smart UCV
  - Fixed UVC (e.g., HVAC systems)
  - Does NOT replace traditional disinfection processes but ADDS to it

Sterilization

- *Definition:* a set of processes that leads to the destruction/elimination of all microbial life
- *Application*: medical devices, supplies, and instruments only
  - Surgical instruments and surgical robotics
  - Certain types of endoscopes
  - Dental instruments
- May be used for other applications like sterilization of medical waste & laboratory specimens (TB)



Types of Sterilization

- Steam sterilization
  - Flash sterilization
- Low-temperature sterilization
  - Ethylene Oxide “Gas”
  - Hydrogen Peroxide Gas Plasma
- Liquid-chemical sterilization
  - Peracetic Acid
- Other technologies

Steam Sterilization

- Moist heat in the form of saturated steam under pressure
  - Most widely used method of sterilization
- Effected by presence of soil and test conditions
- 4 primary parameters of steam sterilization:
  - Steam | Pressure | Temperature | Time
- 2 primary types of steam sterilizers
  - Gravity displacement – steam causes air to be forced out of the drain
  - Prevacuum (dynamic air removal) – air is removed by vacuum
- Flash / Immediate Use Steam Sterilization (IUSS) –
  - A sterilization method that involves the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field.

Quick Reference Card	
Process	**Steam Sterilization**
Microbicidal Activity	• Heat destroys all microbial life
Mode of Action	• **Moist heat** destroys microorganisms by irreversible coagulation and denaturation of enzymes and structural proteins
Use	• All critical and semi-critical medical devices that are heat and moisture resistant • Microbiological waste and sharps containers

Low-temp Sterilization

- Sterilization method for heat and moisture-sensitive medical devices
  - Endoscopes
- Uses chemical sterilants rather than steam to sterilize equipment and instruments
- Primary methods:
  - Ethylene Oxide “Gas”
  - Hydrogen Peroxide Gas Plasma

Ethylene oxide (ETO)

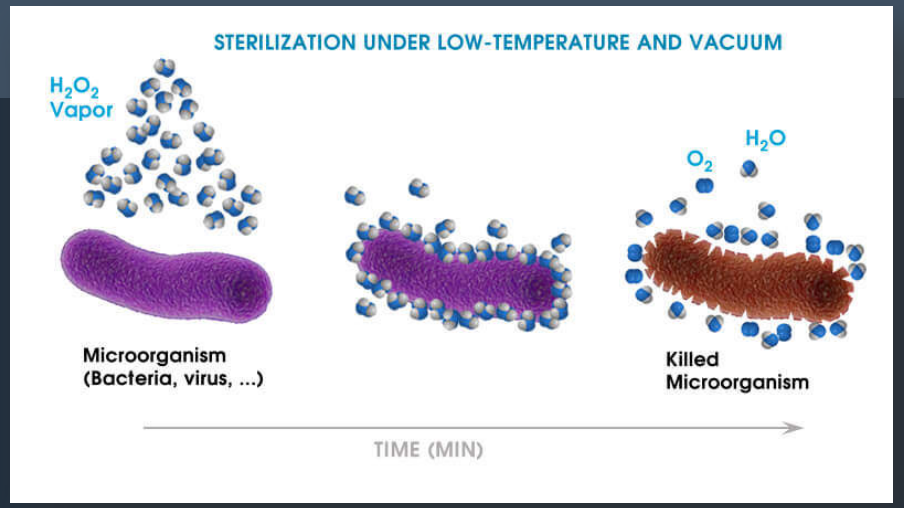
- One of the oldest methods of low-temp sterilization
- Colorless gas that is flammable and explosive
- 4 essential parameters
  1. Gas concentration (450–1200mg/l)
  2. Temperature (37-63C)
  3. Relative humidity (40-80%)
  4. Exposure time (1-6 hours)
- 5 stages
  1. preconditioning and humidification
  2. Gas introduction
  3. Exposure
  4. Evacuation
  5. Air washes

Quick Reference Card	
Process	**ETO**
Microbicidal Activity	• Inactivates all microorganisms including spores
Mode of Action	• **Alkylation** of protein, DNA, and RNA
Use	• Sterilize **moisture or heat sensitive critical and semicritical medical devices**

Advantages	• Penetrates packaging materials and device lumens • Compatible with most medical materials • Simple to operate and monitor
Disadvantages	• Requires aeration time • Potential hazard: toxic, carcinogenic, flammable • ETO emissions regulated • Lengthy cycles

Hydrogen Peroxide "Gas" Plasma (HPGP)

- Gas plasma considered 4th state of matter
- First created in the 1980s
- HP vapor diffuses throughout the chamber then an electrical field is applied to create gas plasma which forms "free radicals"



Quick Reference Card	
Process	**HPGP**
Microbicidal Activity	• Inactivates all microorganisms including spores
Mode of Action	• Combined use of hydrogen peroxide gas and **free radicals**
Use	• Sterilize **moisture or health sensitive critical and semicritical medical devices,** including plastics, electrical devices and corrosion-susceptible metal alloys

Advantages	• Safe for the environment • No toxic residues • Quick cycle time • Compatible with most medical devices
Disadvantages	• Cellulose, linens, and liquids can't be sterilized • Internal lumen diameter restrictions • Special packaging required • May be toxic at greater concentrations

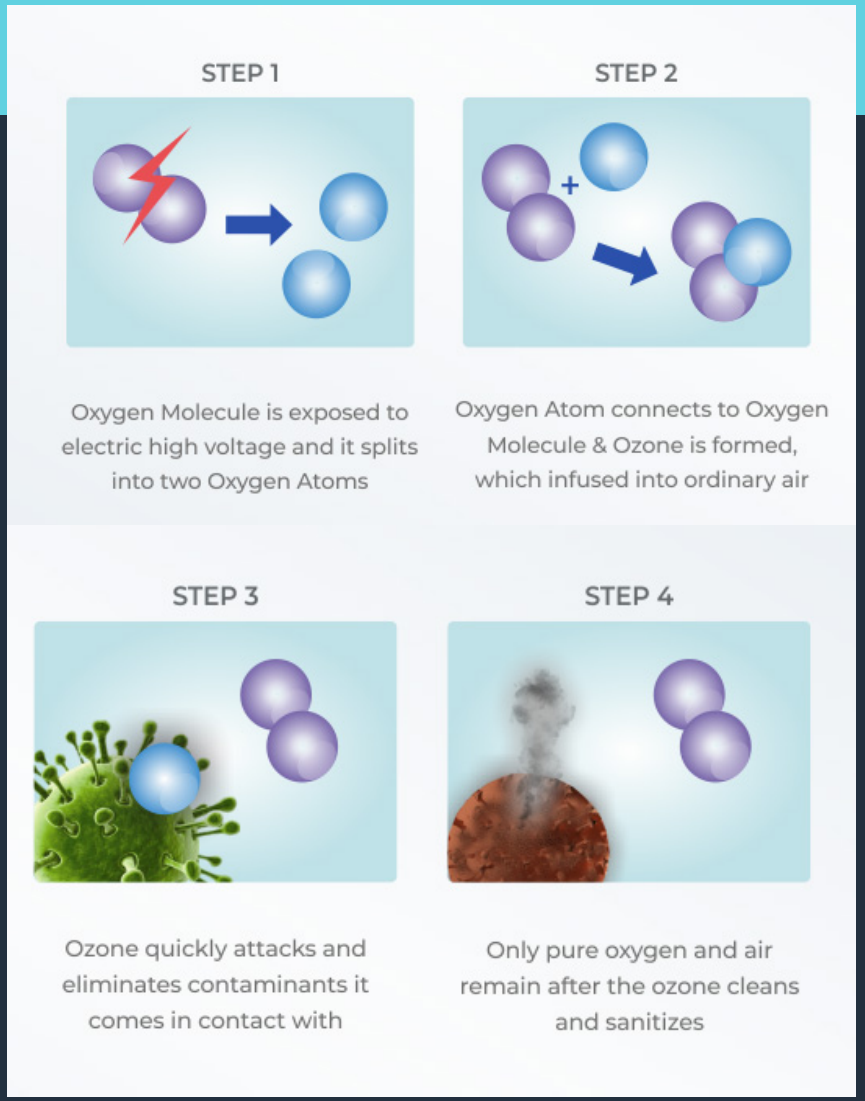
Liquid Chemical Sterilization

- Two step process:
  1. Treatment with *liquid* chemical germicide
  2. Rinsed with water to remove chemical residue
- Can this really be considered “sterilization” if we contaminate the device immediately with water?
  - FDA has weighed in – for use only on semi-critical and critical devices that are heat sensitive and have no approved low-temp sterilization method
- Example: Peracetic Acid (PAA)
  - Inactivates all microorganisms through oxidation
  - Works in the presence of organic and inorganic material

Quick Reference Card	
Process	**Peracetic Acid**
Microbicidal Activity	• Inactivates all microorganisms including spores
Mode of Action	• **Oxidizing agent**
Use	• Primarily **liquid chemical sterilization** of endoscopes

Other Sterilization Technologies

- Ozone
  - Low temp sterilization
  - Ozone generated from oxygen and water
  - FDA cleared for metal and plastic instruments
  - Limited clinical use due to lack of data
- Pasteurization
  - Reusable respiratory equipment

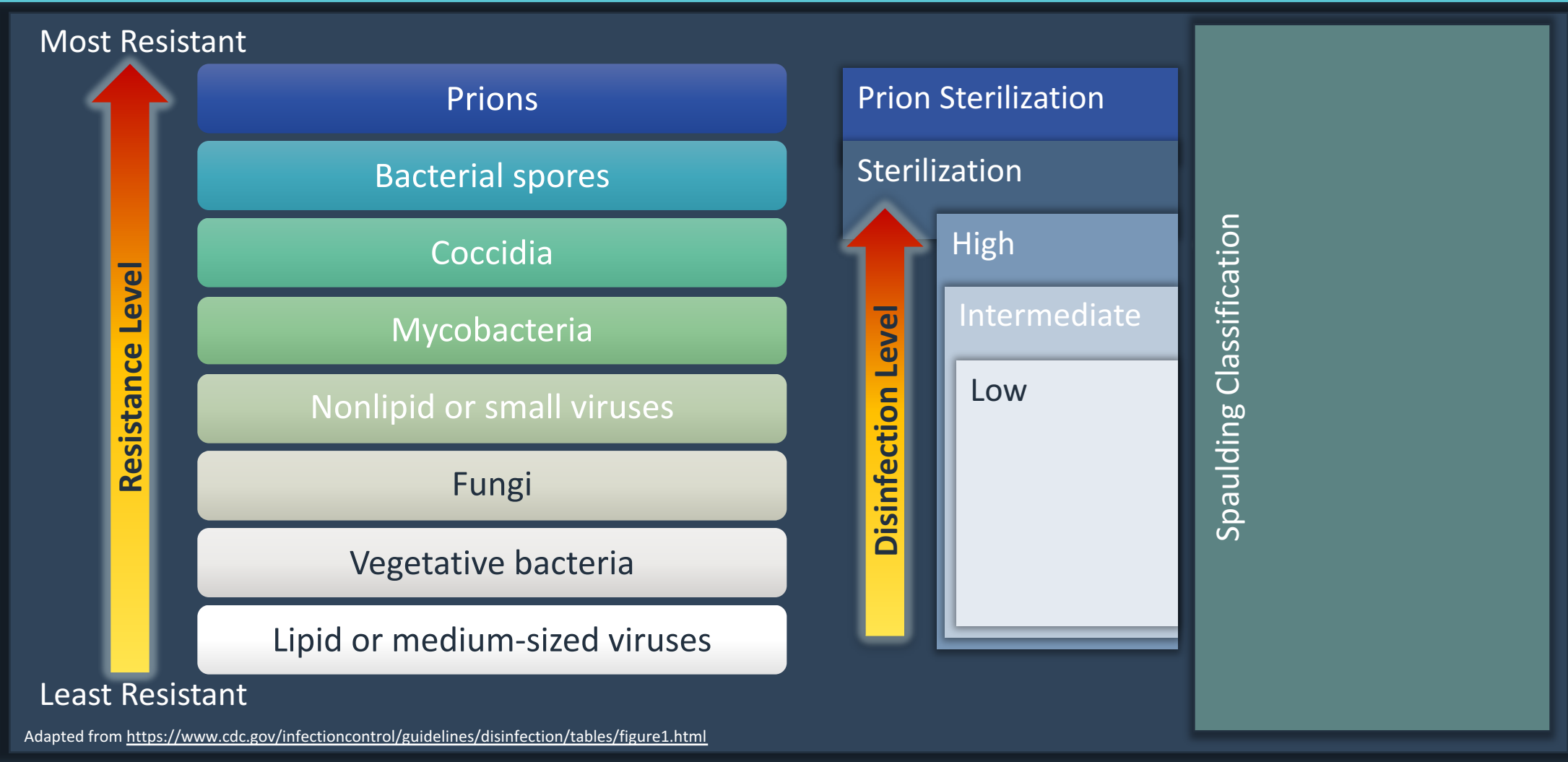


Factors Effecting Performance Efficacy

- Number and location of microorganisms
- Innate resistance of microorganisms
- Concentration and potency of chemical
- Physical and chemical factors
- Organic and inorganic matter
- Duration of exposure
- Biofilms

Adapted from Efficacy | Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC

Level of Disinfection

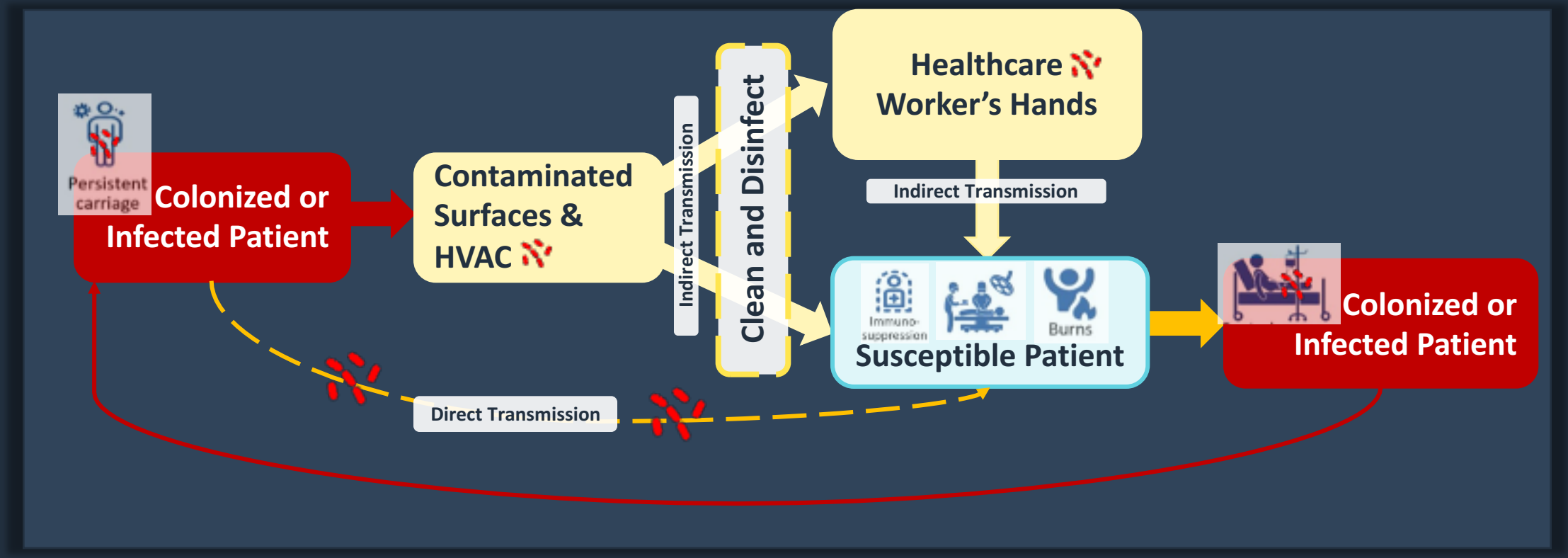


Adapted from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/figure1.html

Environmental Infection Control

Environmental Cleaning and Disinfection

How does the environment play a role in infection transmission?

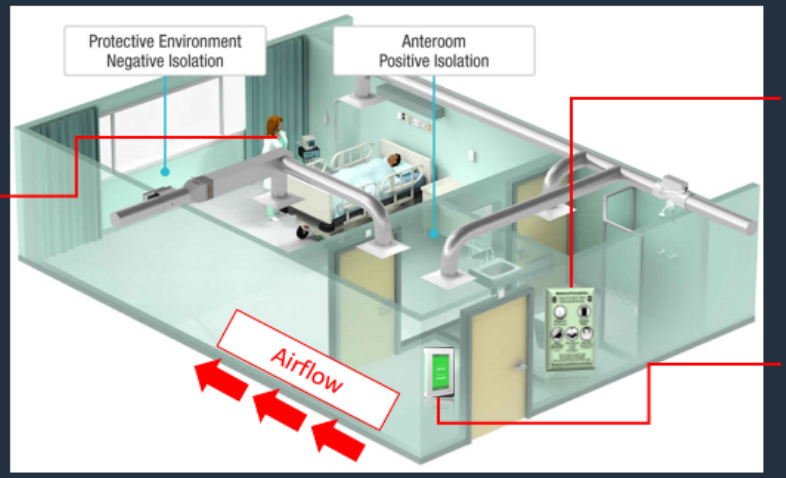


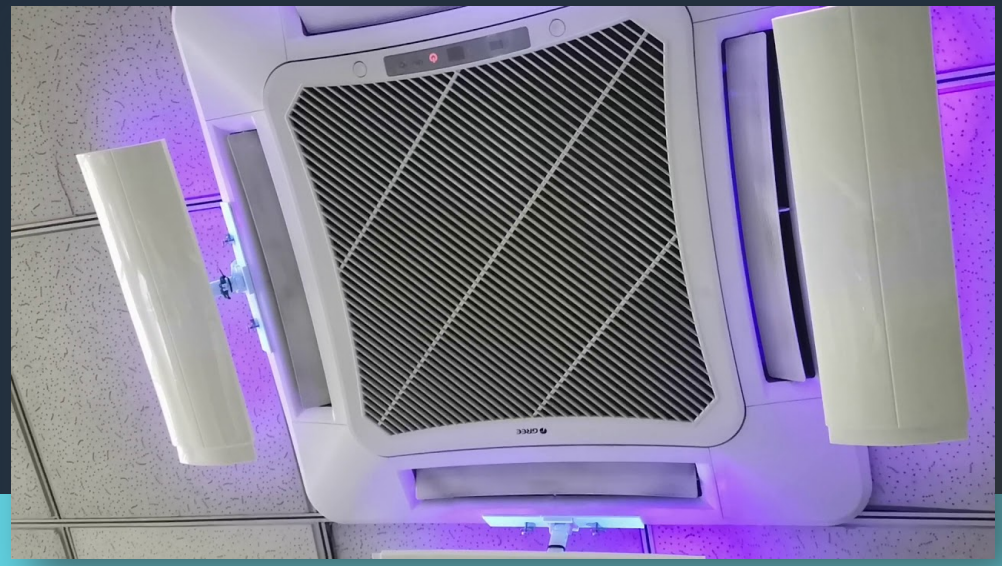
Environmental Infection Control - Air

"The Built Environment"

- The physical space we occupy plays a role in health outcomes

- Air-handling system
  - Pressure gradients, air exchange, and temperature/humidity
- Common air-related pathogens: mold and fungi, airborne transmission of infectious organisms (e.g., tuberculosis)
- Plays a significant role for:
  - Construction projects
  - Operating Rooms & Sterile Processing Departments
  - Specialty Units (e.g., bone marrow transplant units)
- Ultraviolet Disinfection (UVC or UVGI)





Environmental Infection Control - Water

CMS - Water management

- Pathogens of interest:
  - Legionella
  - Pseudomonas spp.
  - Mycobacteria (NTM)
- Primary principles:
  - Water temperature
  - Water stagnation
  - Water disinfection
  - System maintenance

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-*Hospitals/CAHs/NHs*
REVISED 06.09.2017

DATE: June 02, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)
****Revised to Clarify Provider Types Affected****

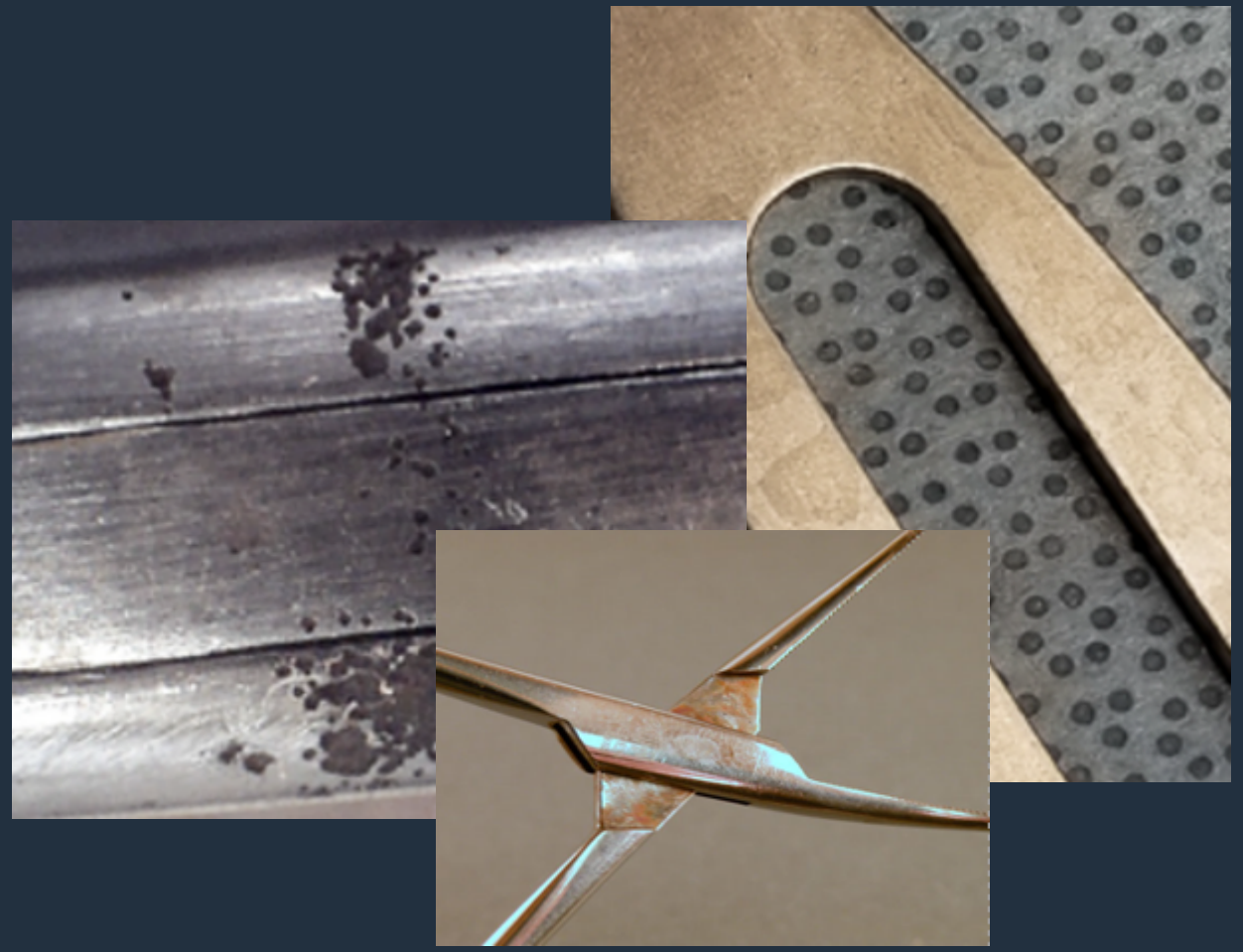
Memorandum Summary

- ***Legionella* Infections**: The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.
- **Facility Requirements to Prevent Legionella Infections:** Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of *legionella* and other opportunistic pathogens in water.
- *This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.*

Environmental Infection Control – Water Quality

Water also effects instrument reprocessing which is very important for patient-ready equipment

- Can cause staining, rusting, and pitting of surgical instruments
  - Inorganic compounds
  - pH
  - Residuals
  - Impurities
- Soiled instruments can lead to immediate jeopardy findings during regulatory surveys



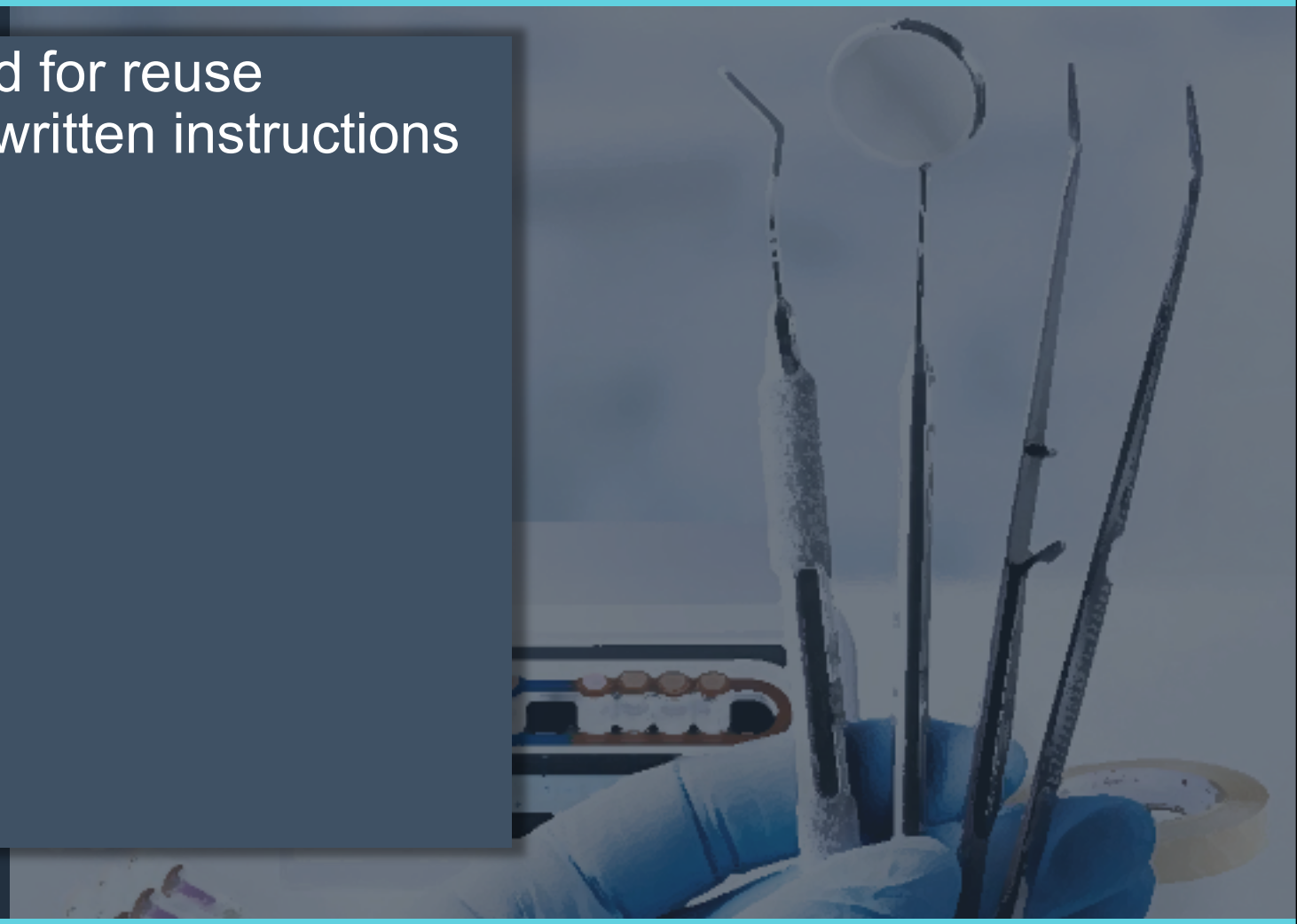
Environmental Infection Control – Environmental Surfaces

- Low level and intermediate level disinfection
- Very important to prevent indirect, horizontal transmission of microorganisms
- High-touch or touchable surfaces
  - Bed Rails
  - Bed Frames
  - Moveable lamps
  - Tray table
  - Bedside table
  - Handles
  - IV Poles
  - Blood-pressure cuff
- Microbes multiply very quickly – environmental cleaning and disinfection help keep the bioburden low which decreases the risk of accidental transmission

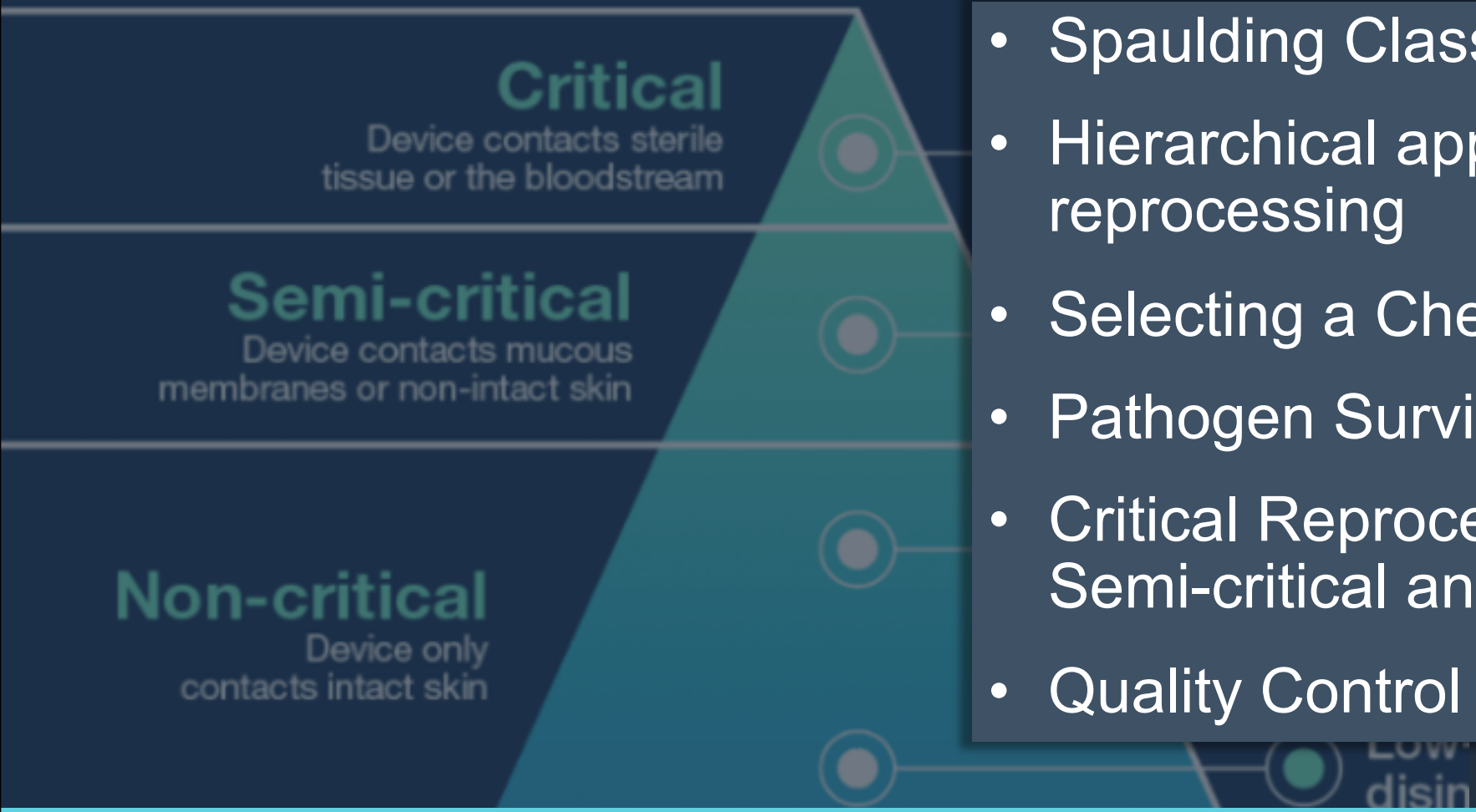
Reprocessing of Medical Equipment

Reusable Medical Devices

- Medical devices that are intended for reuse according to the manufacturer's written instructions for use as approved by the FDA
- *Not all devices are reusable*!
- These can include:
  - Surgical instruments
  - Flexible and rigid Endoscopes
  - Ultrasound probes
  - Glucometers
  - Blood pressure cuffs



Reusable Medical Devices



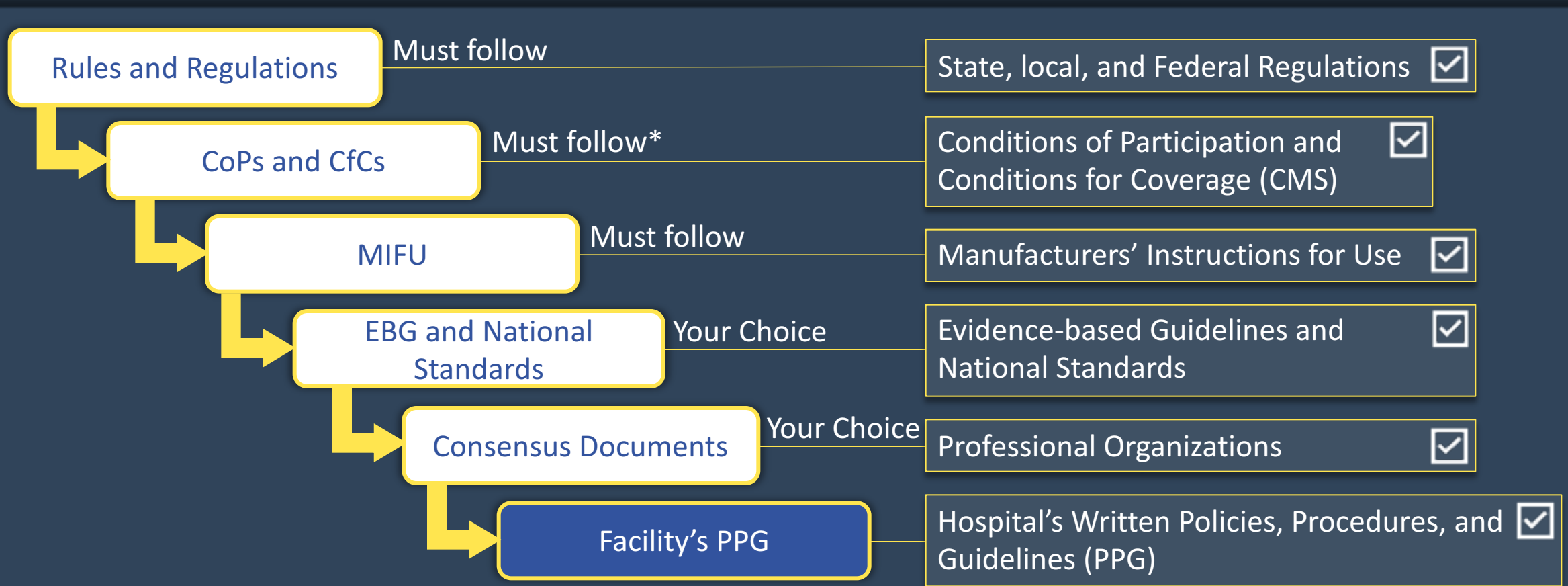
- Spaulding Classification system
- Hierarchical approach to reprocessing
- Selecting a Chemical
- Pathogen Survival
- Critical Reprocessing Steps for Semi-critical and Critical devices
- Quality Control

Spaulding Classification System

Spaulding Classification System – A rational approach to disinfection and sterilization of patient-care items and equipment by classifying medical devices		
Device Classification	**Definition**	**Examples**
Non-critical	Contact intact skin, but not mucus membranes	Blood pressure cuff Bedpans Crutches
Semi-critical	Contact mucous membranes or nonintact skin	Endocavity Ultrasound Probes Flexible Endoscopes Optical Tonometers
Critical	Enter sterile tissue or the vascular system	Surgical Instruments Central Venous Catheters Surgical Implants

Patient Safety RISK

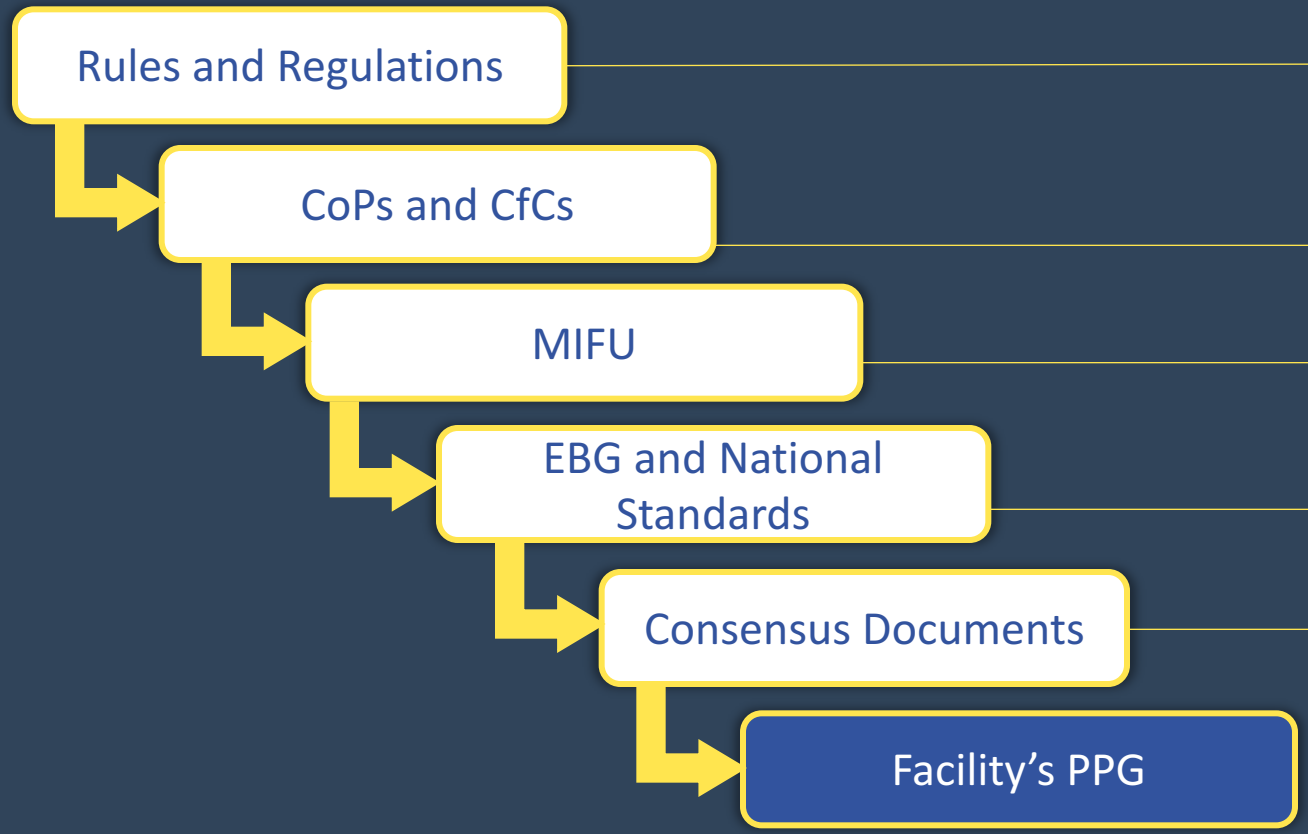
Hierarchical Approach to IPC Policy for Reprocessing



*For facilities that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, CoPs and CfCs should be reviewed

Adapted from The APIC/JCR Infection Prevention and Control Workbook, 4th Edition, Chapter 8, Figure 8-1, page 195

Example – Quick Safety Issue 65 on Sterile Storage Rooms Requirements



"…Deemed organizations must fulfill Centers for Medicare and Medicaid Services (CMS) ventilation requirements which outline criteria for new or renovated existing facilities (constructed or plans approved on or after July 5, 2016). These are provided in the 2012 edition of NFPA 99 which references the 2008 edition of ASHRAE 170 table 7.1. If your local authority has published building codes, then your organization must meet the most restrictive requirement."

"…CMS requires that sterile packages are stored so that sterility is not compromised, and sterile items are inspected for integrity before use."

"…If, for example, the manufacturer of the sterile supply item requires a specific temperature and humidity requirement for storage, your organization would need to meet that requirement."

"…Most EBGs agree that sterile supply areas must be clean, well ventilated and protect supplies from contamination, moisture, dust, temperature extremes, and humidity extremes. Whether you are storing supplies in a designated Central Medical Surgical Supply Area or in a storage room with mixed clean and sterile supplies, you should store those supplies in a manner to protect from contamination and maintain the integrity of the packaging from damage."

TJC Quick Safety Issue 65:
https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-65/#.YsxTFjfMJaR

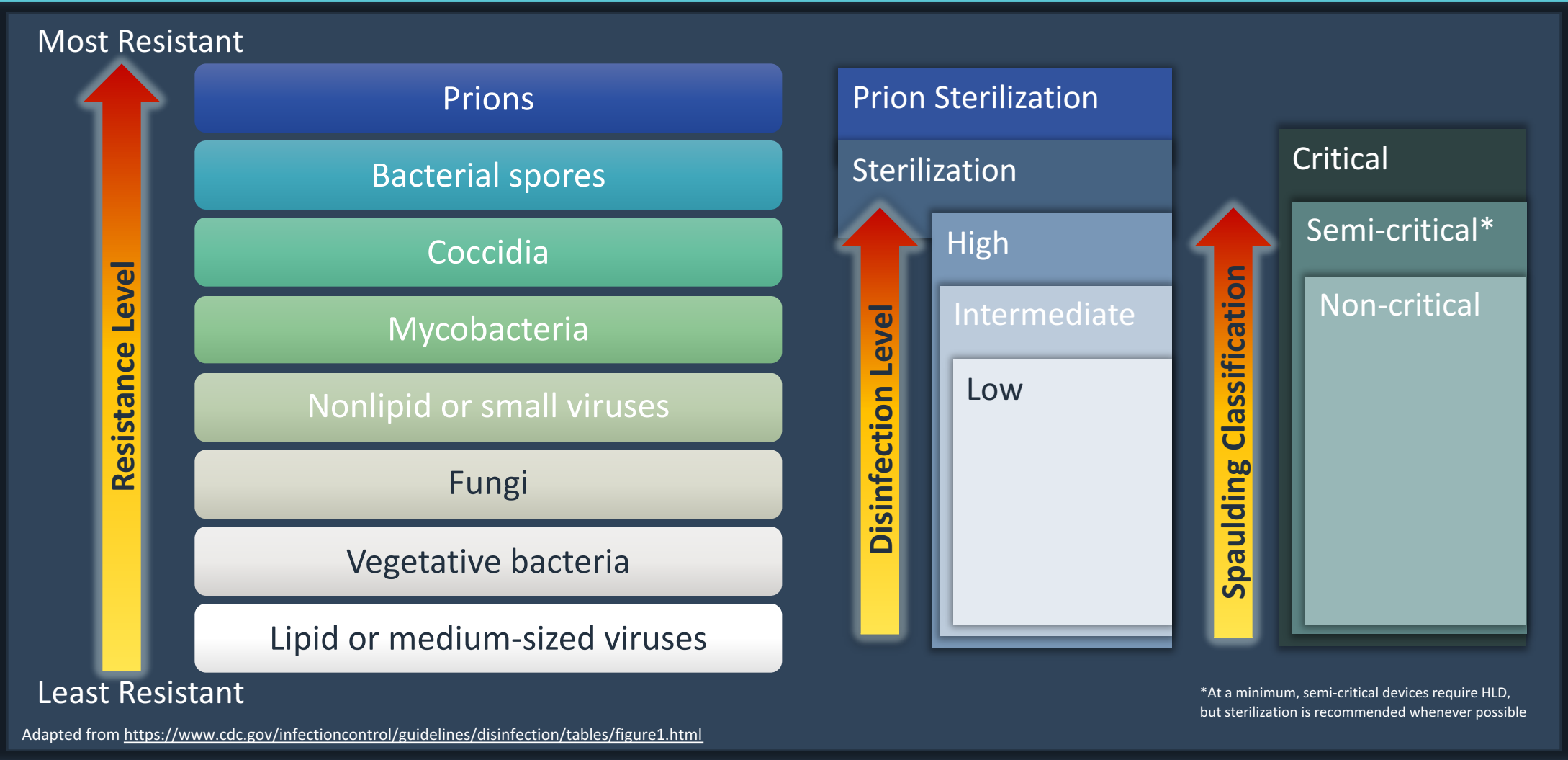
Adapted from The APIC/JCR Infection Prevention and Control Workbook, 4th Edition, Chapter 8, Figure 8-1, page 195

Selecting a Chemical/Disinfectant

Broad Spectrum	Fast Acting	Environmental Factors	Nontoxic	Surface Compatibility
Residual Effect	Easy to Use	Odorless	Economical	Solubility
	Stability	Cleaner	Environmentally Friendly	

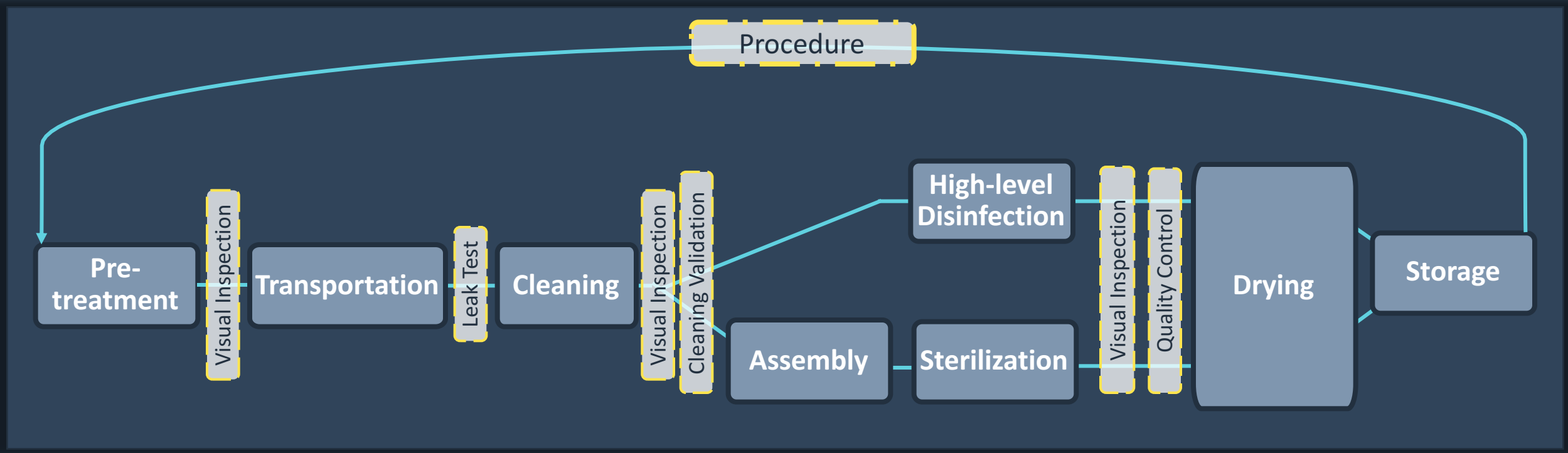
Adapted from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/table2.html

Let's tie it all together!



Adapted from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/tables/figure1.html

High-level overview of reprocessing steps for semicritical and critical medical devices



Pretreatment and Transportation

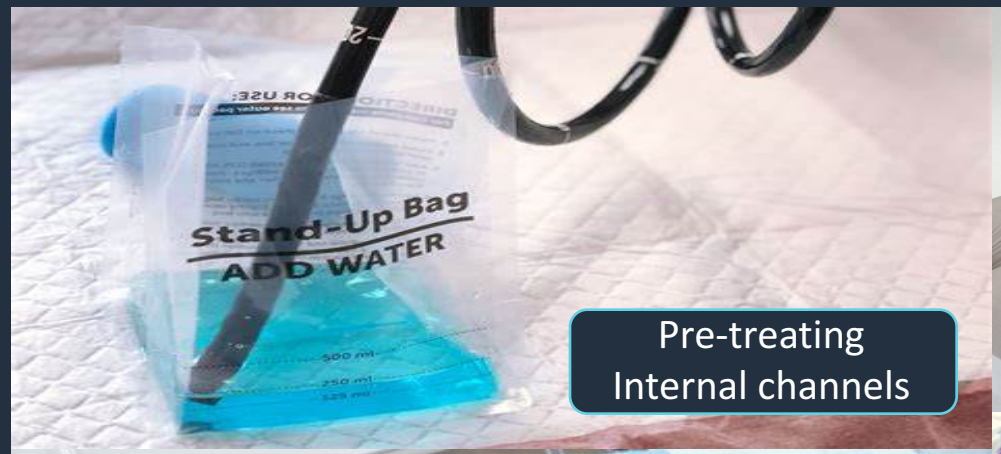
Pretreatment

- Performed as soon as possible after use, ideally at the point of use, and typically with a detergent product that can break down organic soil
- Intended to remove as much *soil* from the device before it has a chance to harden, which would render it much more difficult to clean and disinfect/sterilize

Transport

- Often involves keeping devices moist, possibly a surfactant product, which helps prevent drying as well during transfer to the decontamination area
- For High-level disinfection, we adhere to the "golden hour" which is generally the amount of time you have before additional reprocessing steps are required for cleaning semi-critical devices (e.g., endoscopes) per the manufacturer
- Must transport devices in rigid or leak-proof containers to avoid possible exposure during transport to decontamination area

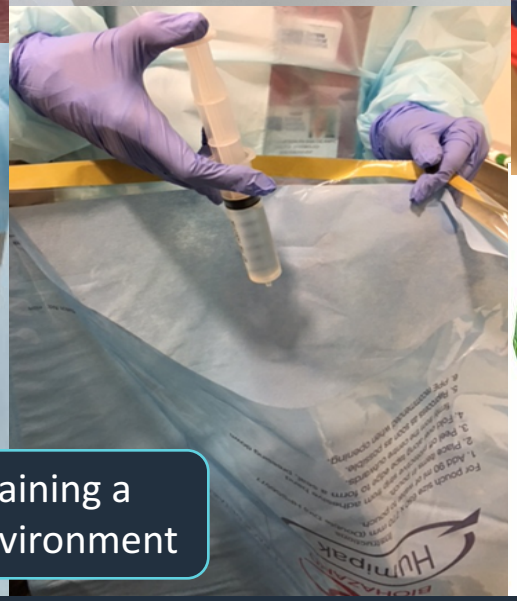
Pretreatment and Transport



Pre-treating Internal channels

Pre-treating External surfaces

Maintaining a moist environment

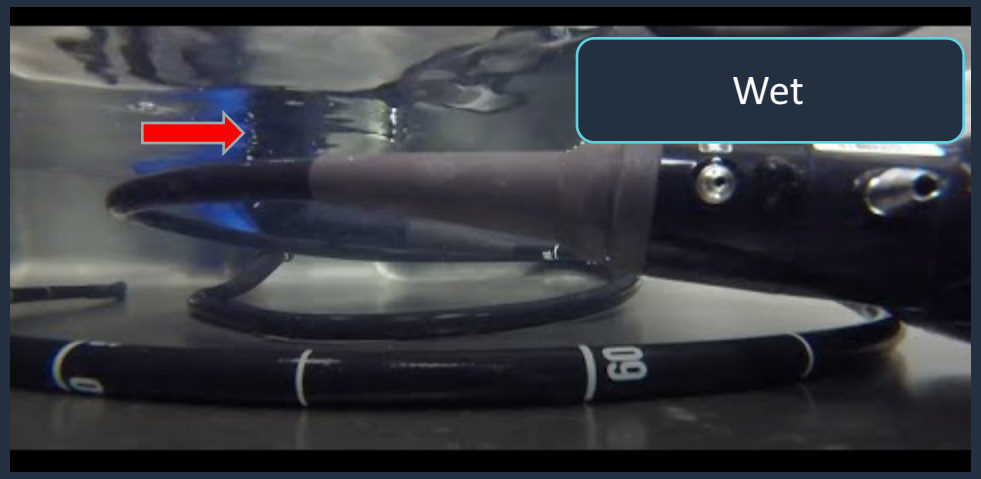


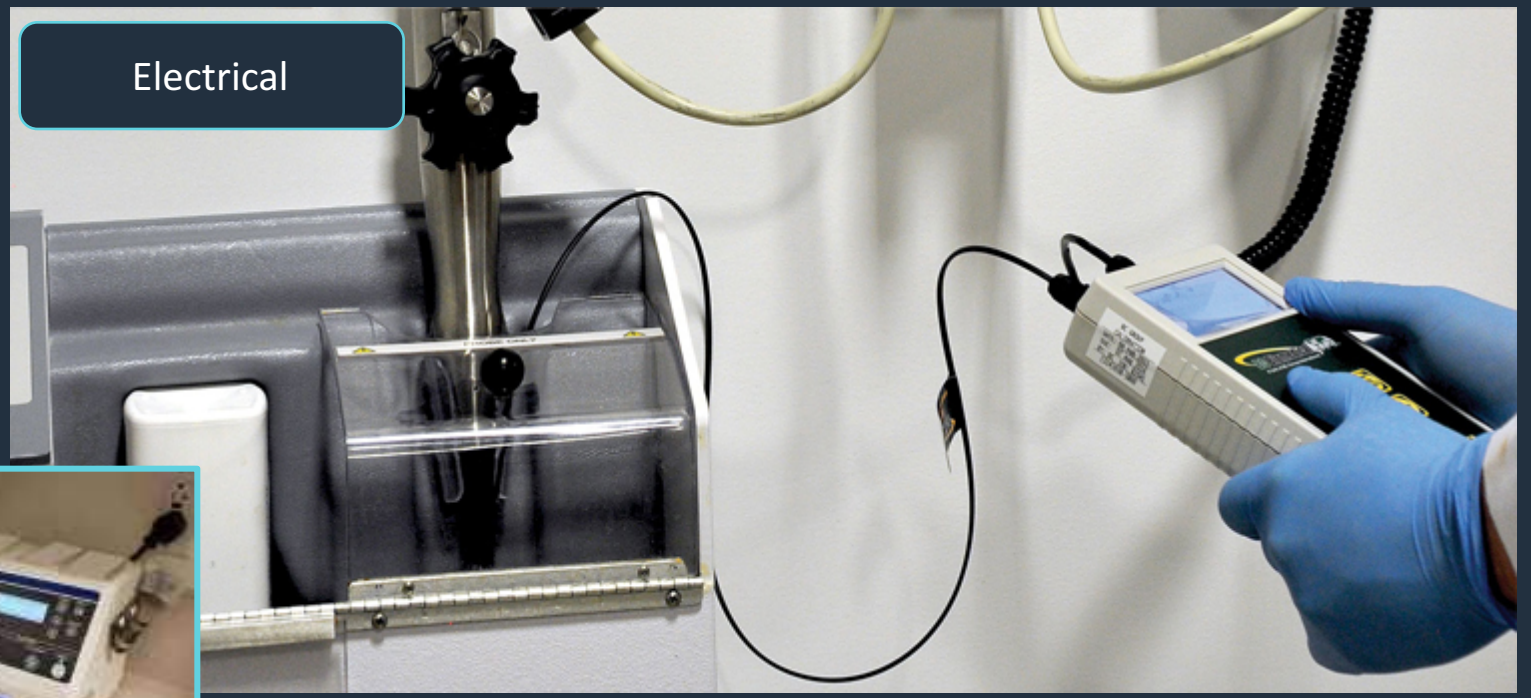
Transport Containers

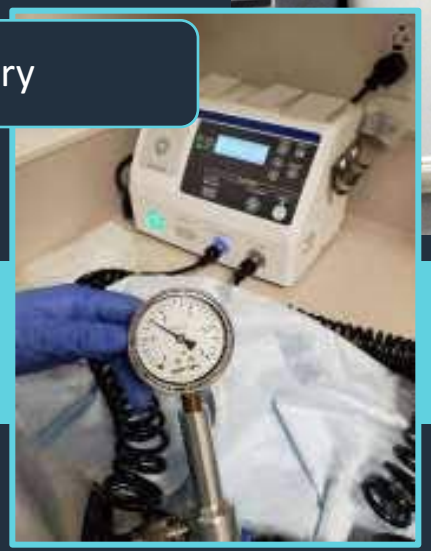
Leak Testing

- Certain devices must be tested for leaks, like endoscopes and certain endocavity ultrasound probes
- Can detect device damage and prevent injury
- Bacteria love cracks and damage (hard to clean)
- Leak testing can be dry, wet, or electrical
  - Submerge under water and observe for bubbles
  - Forced air device reads the internal pressure
  - Electrical current detection
    - For transesophageal electrocardiography probes (TEE)

Leak Testing





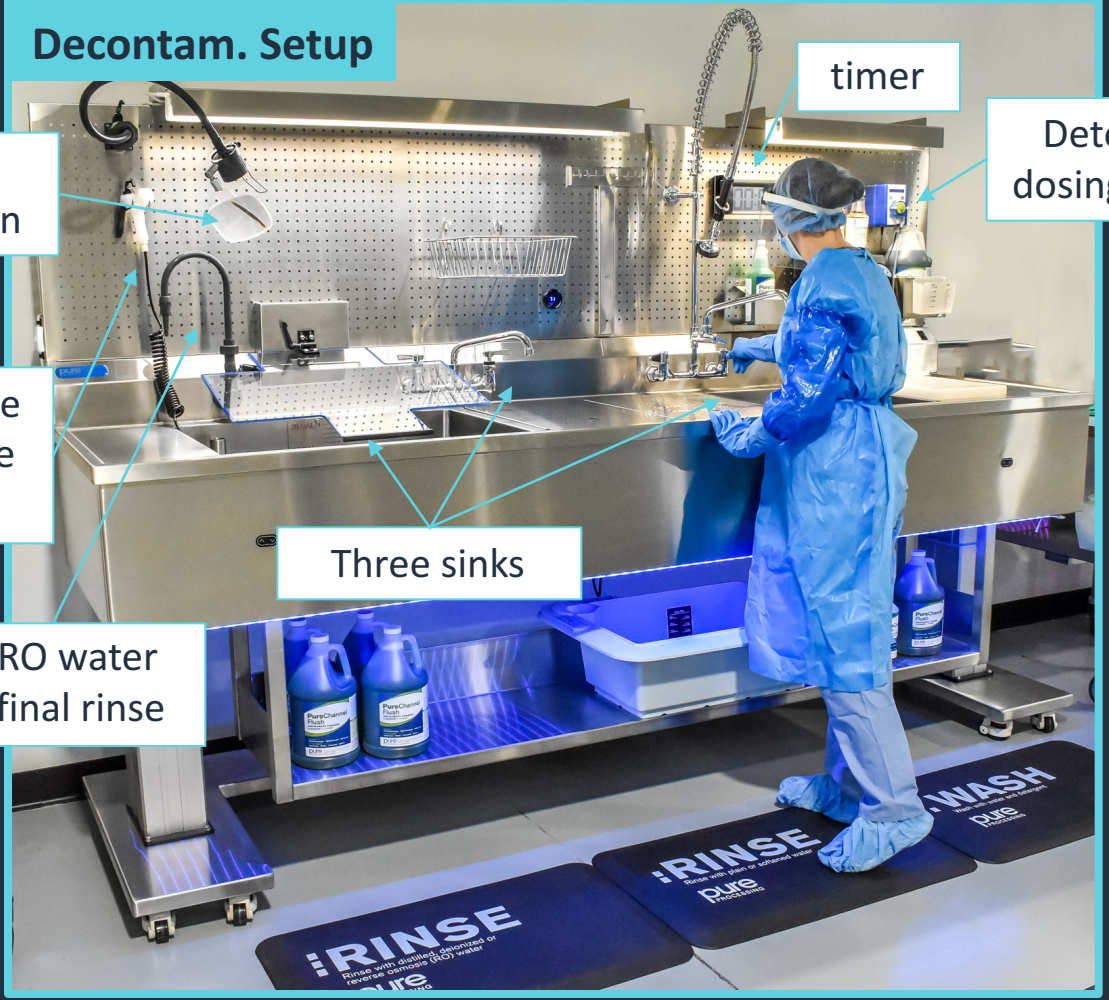


Decontamination (Cleaning)

- Decontamination or *cleaning* of devices is the ***MOST IMPORTANT*** step of instrument reprocessing
  - You can't disinfect or sterilize if the device isn't clean
- Involves further, meticulous use of detergents that help breakdown and remove organic material and soil prior to disinfection and sterilization
- Cleaning can be either manual or mechanical (automated)
  - Friction and fluidics
  - Ultrasonic cleaners or cleaner/disinfectors
- May involve brushing and flushing internal lumens/channels
- Disassembling may be required for complex devices per IFU
- May require monitoring:
  - Temperature, time, and dilution

Decontamination

Decontam. Setup

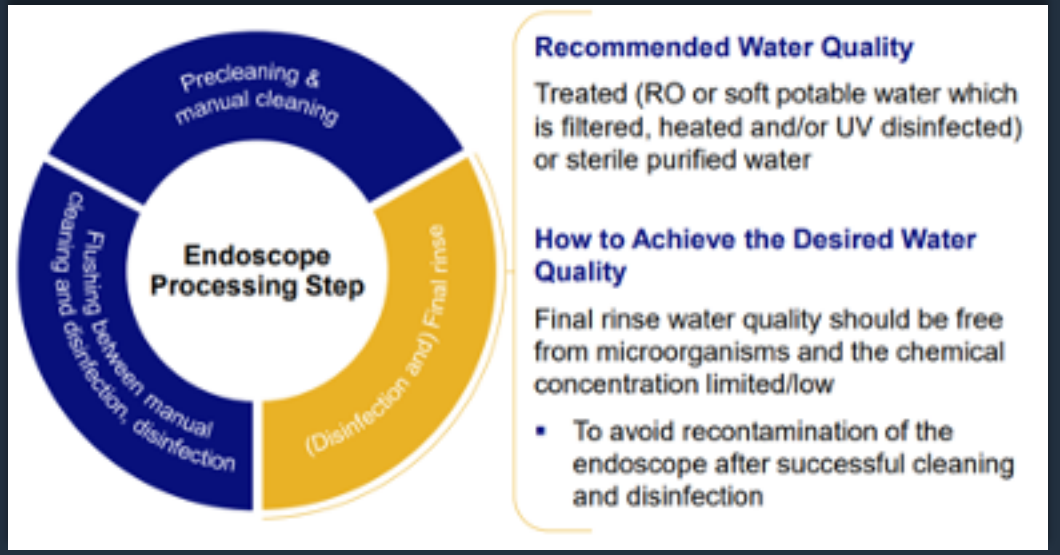


Ultrasonic Cleaner

Brushing Internal Lumens

Disinfection (HLD)

- Use of chemical disinfectants to kill bacteria and other pathogens from semi-critical devices
- High level disinfectants or liquid chemical sterilants
  - **Kill claims** - what pathogens are killed
  - **Dwell time** (wet time) - how long the chemical must remain in contact with the surface to meet a kill claim
  - **Minimum Effectiveness Concentration** (MEC) – Concentration of the disinfectant that must be maintained to meet kill claim when exposed for the appropriate dwell time (Quality Control)
- The disinfectant MIFU should give a minimum temperature and dwell time to be effective which is approved by the FDA
- Can also be manual or mechanical (automated)



https://mdc.olympus.eu/asset/084438885177/d91d4f9b1274d6cd9fb444d094b632d4?content-disposition=inline

Disinfection (HLD)

GUS Station

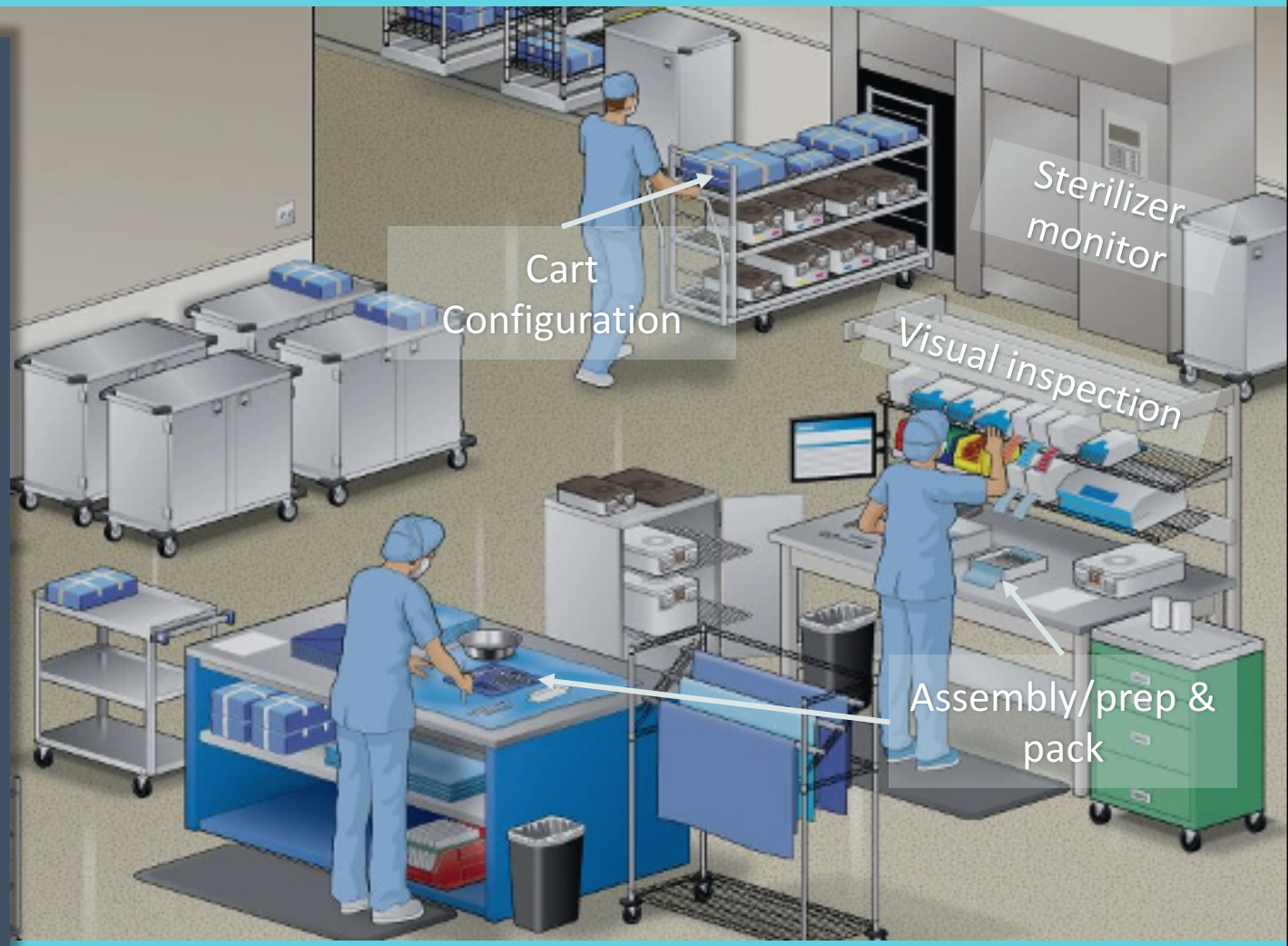
AER

Manual Soak

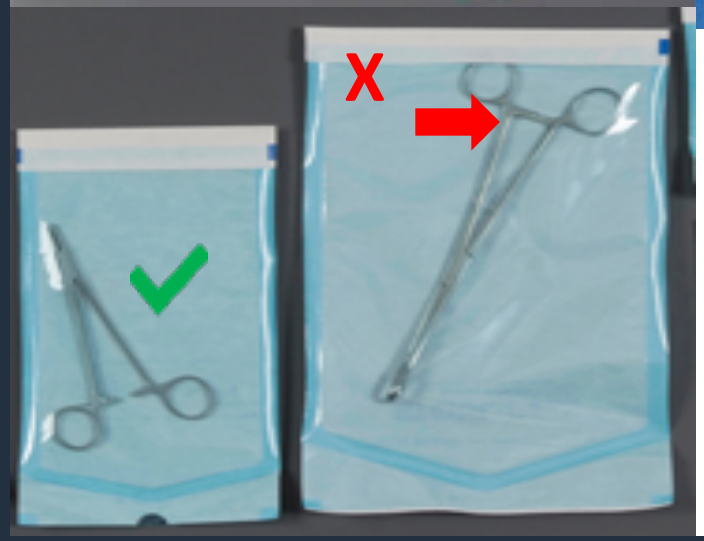
Endocavity US Probe Reprocessor

Sterilization

- Visual inspection
  - Looking for pitting, rusting, staining, etc.
  - Use Lighted magnification and/or Borescope for channeled instruments
- Assembly of instruments
  - Packs, wraps, and trays
- Cart configuration
- Process Monitoring
- QC Results and interpretation



Sterilization




```
========== PREVAC ==========
CYCLE START AT  15:14:55
             ON   8/11/09

CYCLE COUNT          8675
OPERATOR
STERILIZER:  421
CYCLE TYPE   PREVAC
 CYCLE NO.   4

   STER TEMP - 132.2C
CONTROL TEMP - 133.3C
   STER TIME -  4 MIN
    DRY TIME - 40 MIN

                    V-inHg
- TIME          T- C P-psig
C 15:15:17    35.3    0.0P
C 15:16:18   107.6   12.1P
C 15:17:43    85.5   11.1V
C 15:19:19   129.1   26.0P
C 15:21:05    92.7   14.0V
C 15:22:24   130.2   26.1P
C 15:24:09    94.5   15.0V
C 15:25:26   130.2   26.1P
S 15:29:45   132.2   28.3P
S 15:30:45   133.5   29.3P
S 15:31:45   133.1   29.1P
S 15:32:45   133.2   29.0P
E 15:34:34   105.6    3.6P
E 16:14:35    40.2   28.1V
Z 16:16:11    40.9    1.9V

LOAD              081106

  TEMP MAX-133.5C
  TEMP MIN-132.2C

CONDITION    - 0:14:28
STERILIZE    - 0:04:00
EXHAUST      - 0:42:26
TOTAL CYCLE  - 1:00:54

=    READY TO UNLOAD    =
```

Storage

- Determined by:
  - Reprocessing method
  - Instructions for use
  - Consensus documents/guidelines chosen
- Must avoid cross-contamination and damage
- For high-level disinfected instruments:
  - General expiration is 7-10d
- For sterilized instruments:
  - In general, no expiration unless otherwise indicated
  - Expiration is considered ***Event related***

Quality Control and Assurance

Depends on the processes being performed

- Cleaning
  - ATP testing – detects the presence of organic soil
  - Protein residue testing
- Disinfection
  - Chemical indicators for concentration testing
  - Surveillance Cultures
  - QA of test strips to ensure that the test strips are working properly
- Sterilization
  - Chemical indicators and biological indicators
    - Sterilization parameters and lethality monitoring
  - Event related sterility

ATP Testing and Surveillance Culture Sampling

ATP Testing

- Detects the presence of Adenosine Triphosphate which is present in organic soil
- Great process to use to determine if something has been cleaned well or needs to be cleaned again
  - does NOT test for quality of disinfection practices

Surveillance Culture Sampling

- May collect cultures/surveillance swabs of high-risk endoscopes (i.e., duodenoscopes) after disinfection to determine if the endoscope has viable growth of MDROs
- Requires laboratory partnership to identify organisms, particularly CRE isolates

Quality Control - Chemical Indicators

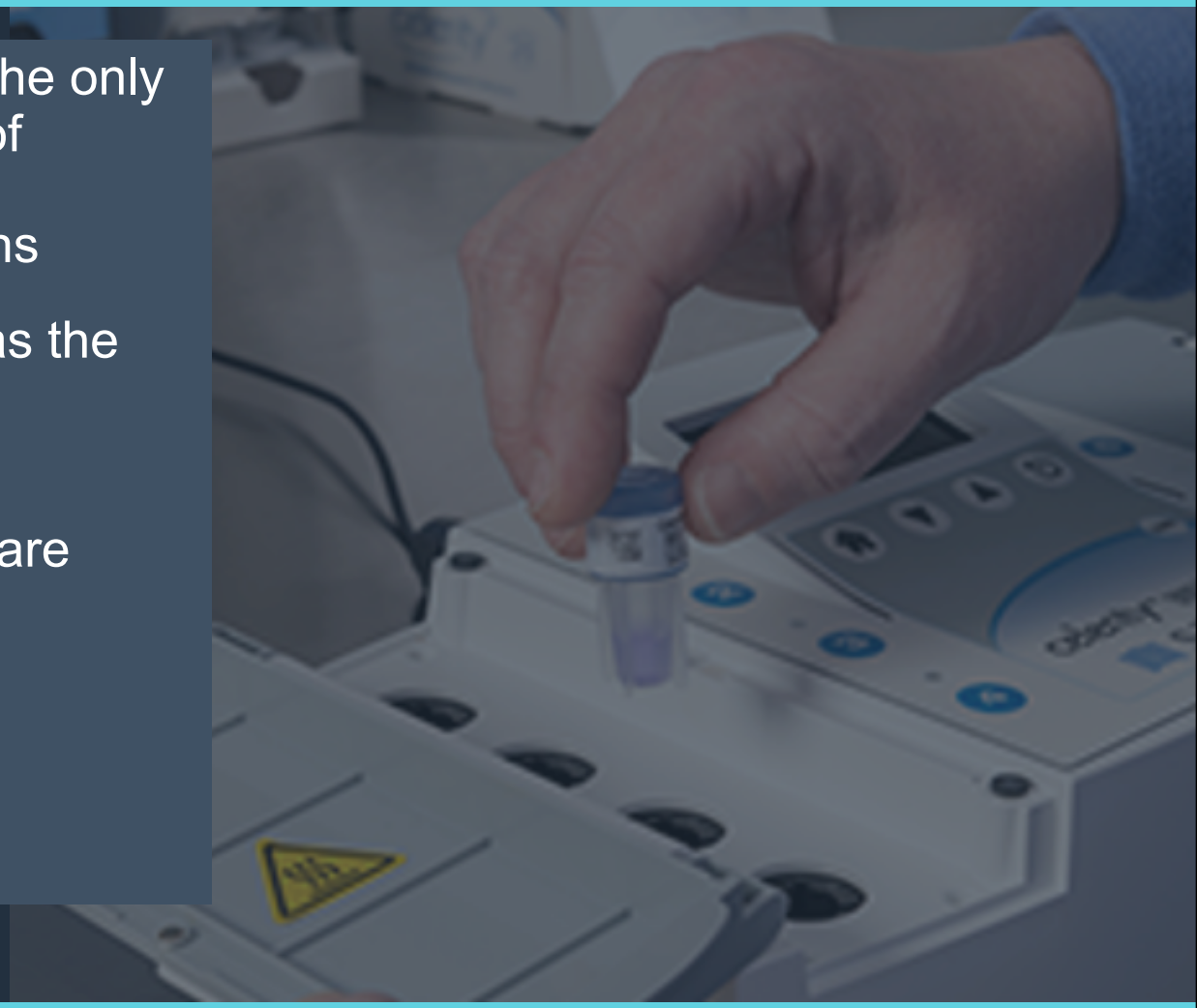
Class	What they indicate	Example
Class I: Process	One or more critical variables (e.g., Steam exposure)	Autoclave tape
Class II: Specific-use	Specific sterilization processes/tests	Bowie-dick test for dynamic air removal sterilizers
Class III: Single-Variable	One critical variable (e.g., Temp)	Chemical pellet that melts at a specific temp.
Class IV: Multi-variable	Two or more critical variables (e.g., Time/Temp)	Chemical indicator tubes that react at specific time and temp
Class V: Integrating	All critical variables (Time, Temp, Steam)	Chemical Integrators
Class VI: Emulating	All critical variables for specific cycle types	Cycle-specific indicators (e.g., 15 min sterilization at 121C)

Sterilizer tape

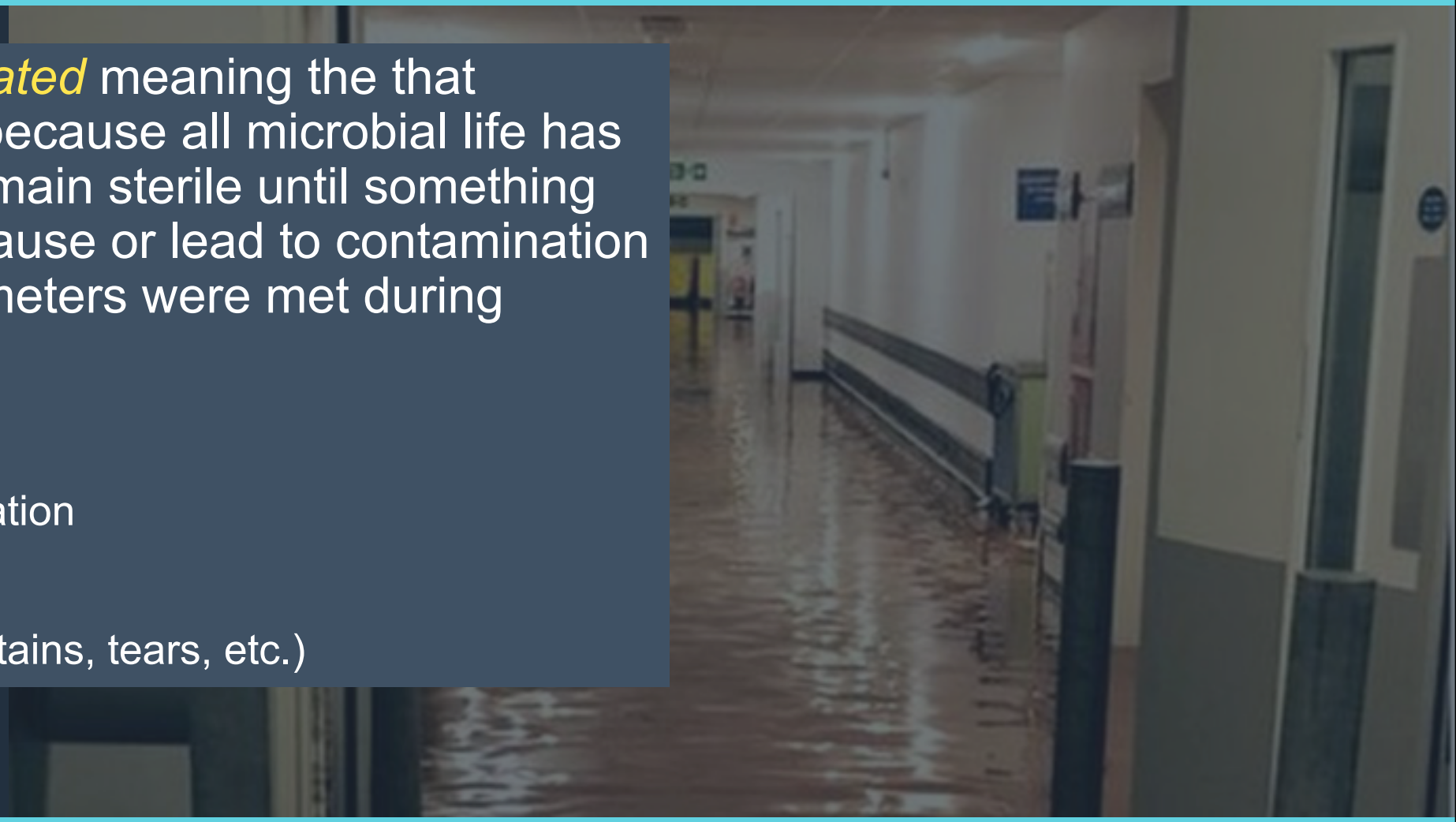
Bowie-dick test

Quality Control - Biological Indicators (BIs)

- BI's are ideal monitors of sterilization as they are the only process indicators that directory monitor *lethality* of sterilization against the most resistant form of microorganisms (bacterial spores) other than prions
- Manufacturer specific – you can't mix and match as the manufacturer's have tested specific BI's with their instruments
- Incubation used to take up to 7 day – now results are available in as little as 20 mins
- Examples:
  - *G. stearothermophilus* spores (Steam)
  - *B. atrophaeus* spores (ETO)



Quality Control - Event Related Sterility

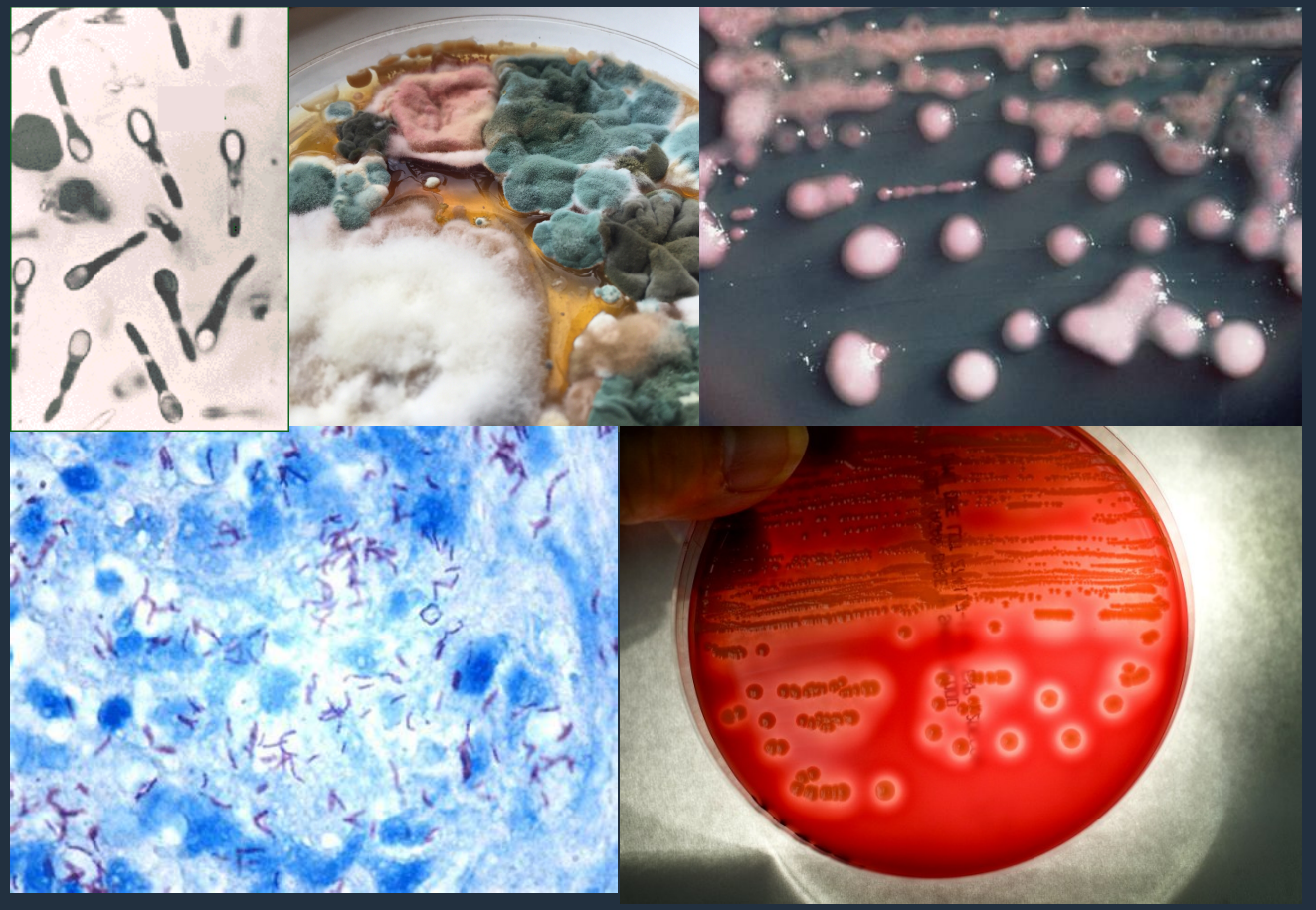


- Sterility is *event-related* meaning the that sterilized devices (because all microbial life has been destroyed) remain sterile until something happens that can cause or lead to contamination (assuming all parameters were met during sterilization)
- Examples:
  - Temperature fluctuation
  - Humidity changes
  - Integrity/damage (stains, tears, etc.)

What can happen when we miss the mark?

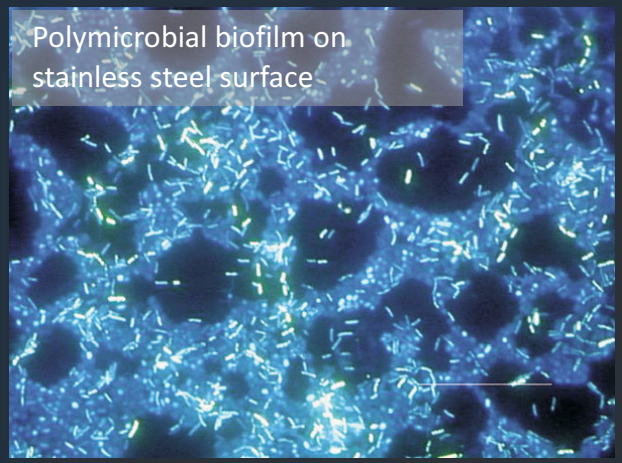
Healthcare-Associated Infections

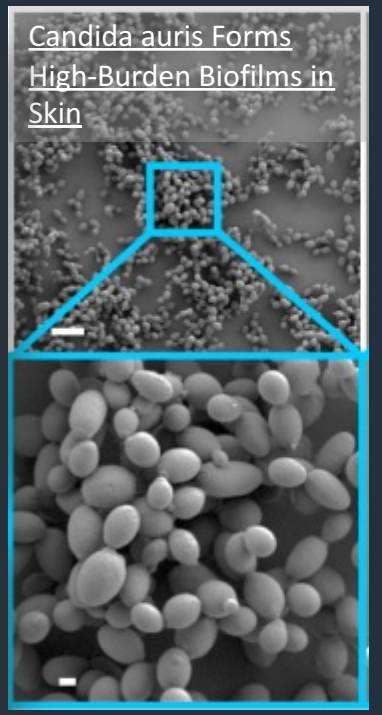
- MRSA/MSSA
- CDI
- Candida auris
- MDR Acinetobacter
- NTM
- MDR Pseudomonas
- CRE
- MTB
- Bloodborne pathogens

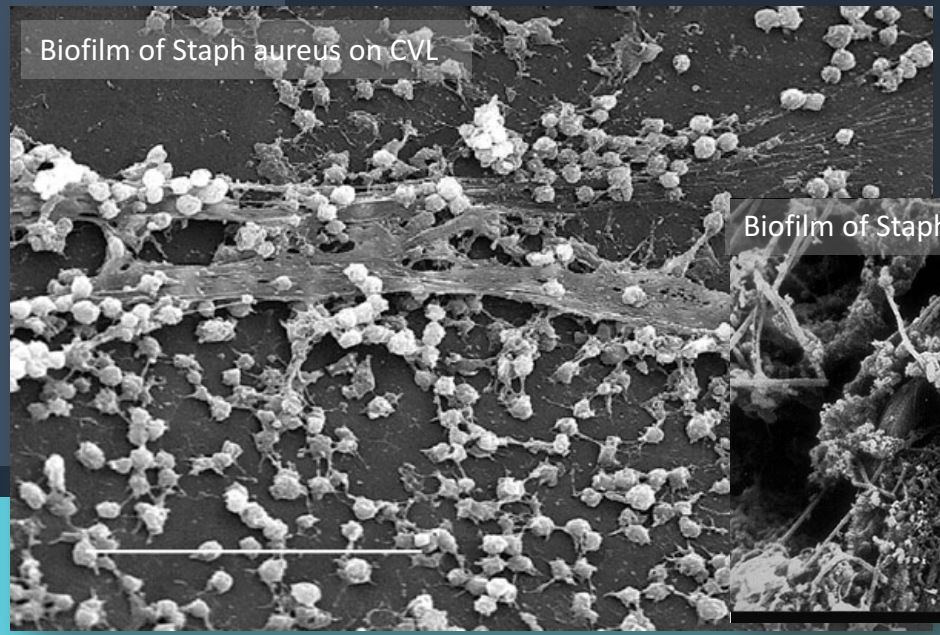


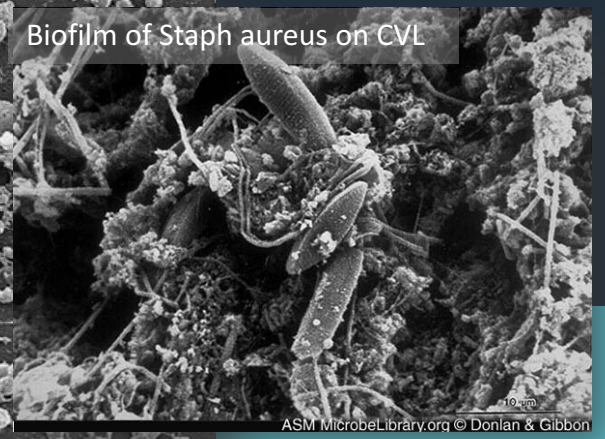
Biofilm Formation

- Per CDC: *"An assemblage of microbial cells that is irreversibly associated with a surface and enclosed in a matrix of primarily polysaccharide material"*
- Solid-liquid interface provides a perfect environment for biofilm formation
- Provides physical protection, genetic resistance, enzyme production, physiologic gradients (e.g., pH)
- Public Health Concerns:
  - Detachment of aggregates
  - Antimicrobial resistance
  - Endotoxin formation
- Drying, damage, poor manual cleaning









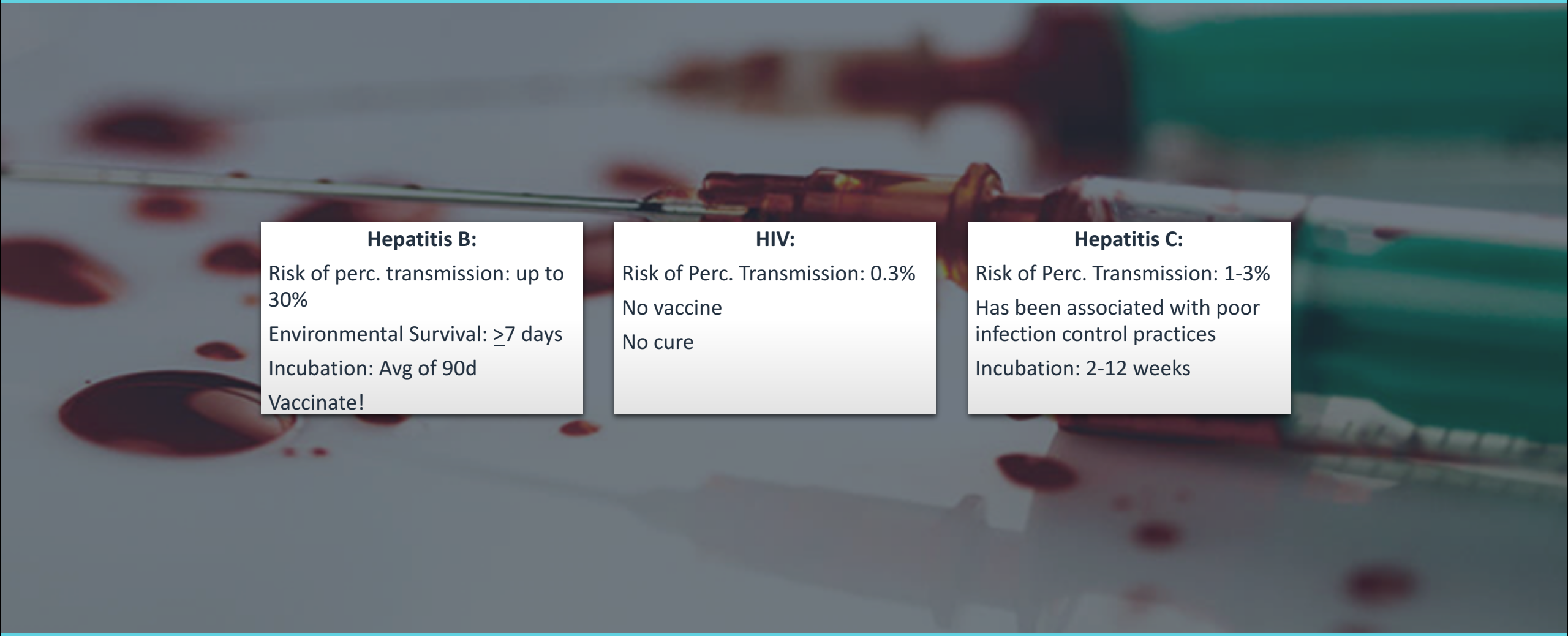
https://wwwnc.cdc.gov/eid/article/8/9/02-0063_article

Carbapenem Resistant Enterobacterales (CRE)

- Systematic review published in 2016 by O'horo et al. found several incidents of device-related transmission of CRE, particularly resulting from improperly reprocessing endoscopes:
  - Duodenoscopes (ERCP)
  - Cystoscopes
  - Uteroscopes
- Reasons included protocol changes, cleaning deficiencies & improper HLD practices likely due to poor understanding of practices and complex design of these devices
- Has led to several safety alerts and an increased focus by accrediting agencies on proper reprocessing

O'Horo, J. C., Farrell, A., Sohail, M. R., & Safdar, N. (2016). Carbapenem-resistant Enterobacteriaceae and endoscopy: An evolving threat. *American journal of infection control*, *44*(9), 1032–1036. https://doi.org/10.1016/j.ajic.2016.03.029

Bloodborne Pathogen Exposure



Hepatitis B:

Risk of perc. transmission: up to 30%

Environmental Survival: ≥7 days

Incubation: Avg of 90d

Vaccinate!

HIV:

Risk of Perc. Transmission: 0.3%

No vaccine

No cure

Hepatitis C:

Risk of Perc. Transmission: 1-3%

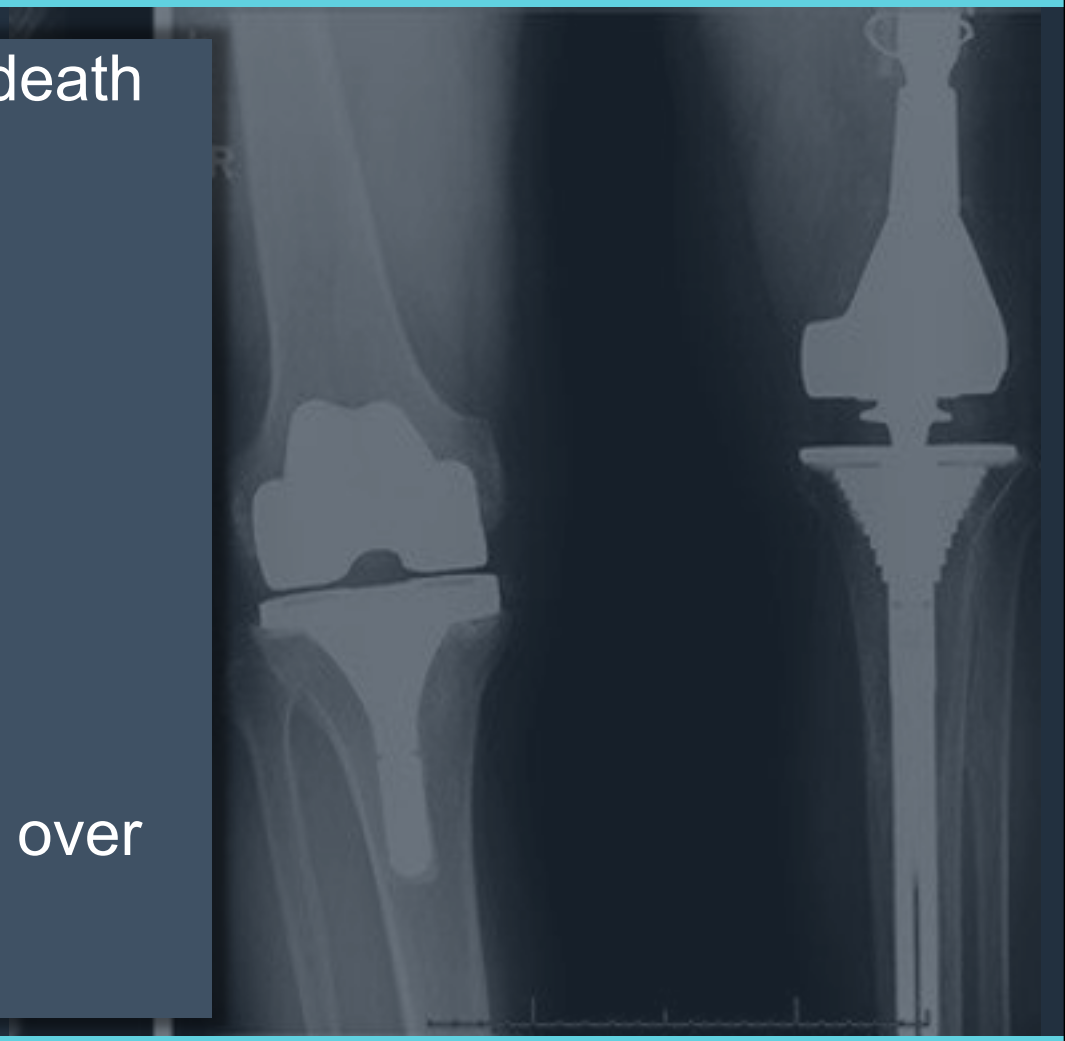
Has been associated with poor infection control practices

Incubation: 2-12 weeks

https://www.cdc.gov/niosh/topics/bbp/default.html

Surgical Site Infections

- Major source of morbidity, economic cost, and death
- Account for 25% of all healthcare associated infections[1]
- Probability of infection results from:
  - Microbial inoculum
  - Virulence
  - Microenvironment of the wound
  - Efficiency of host defenses
- Cost is variable but can be between $10,000 to over $90,000 if associated with a joint infection or multidrug resistant bacteria[2]



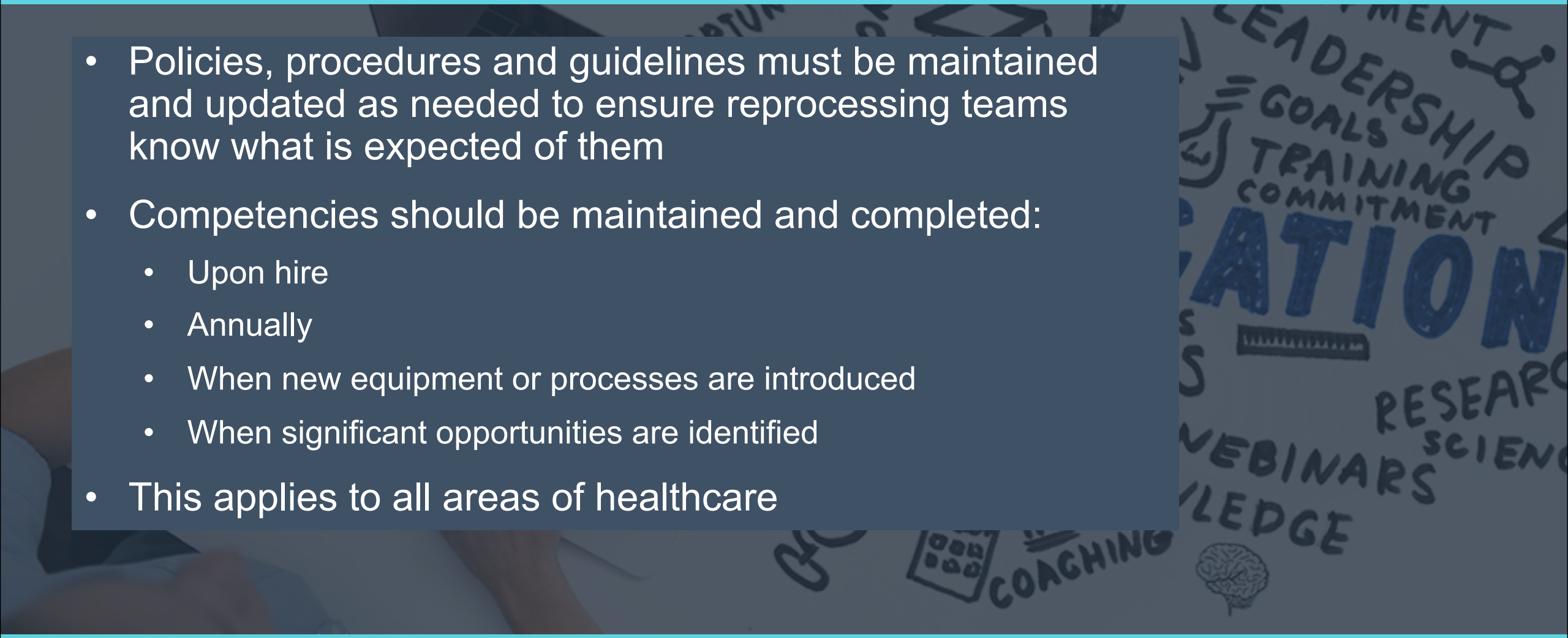
[1]https://www.phc4.org/reports/hai/09/docs/hai2009report.pdf

[2]Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 | Critical Care Medicine | JAMA Surgery | JAMA Network

How do we prevent error?

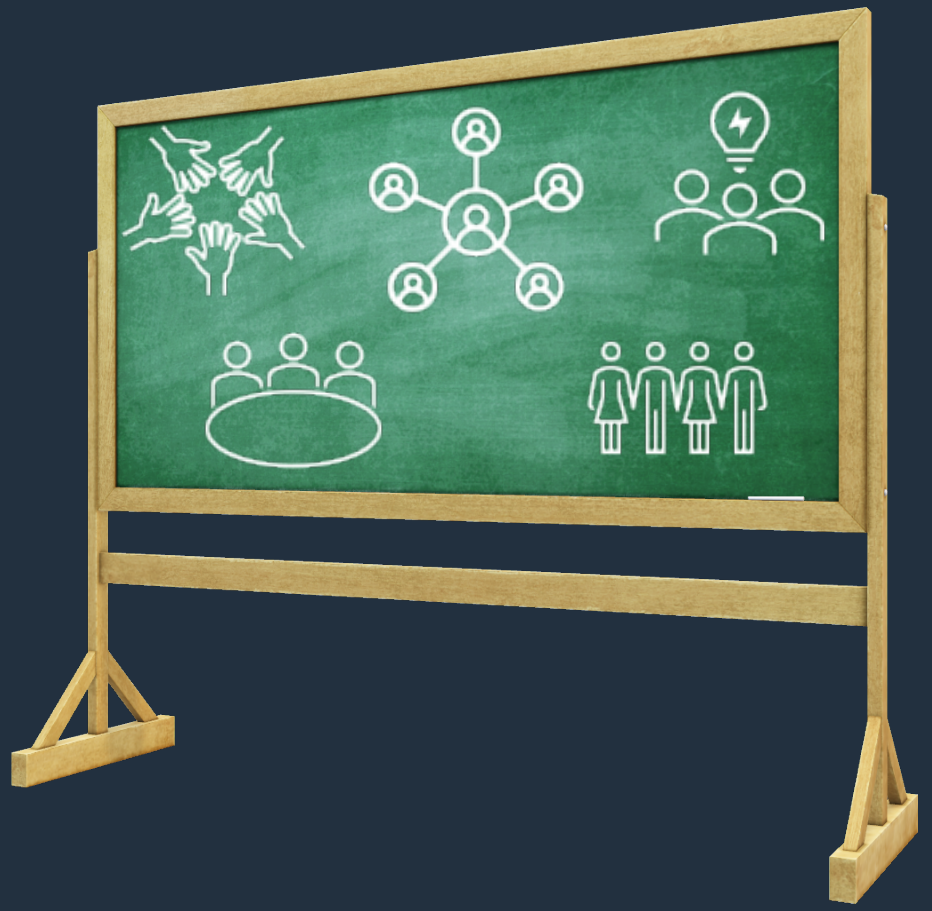
Policies and Competencies

- Policies, procedures and guidelines must be maintained and updated as needed to ensure reprocessing teams know what is expected of them
- Competencies should be maintained and completed:
  - Upon hire
  - Annually
  - When new equipment or processes are introduced
  - When significant opportunities are identified
- This applies to all areas of healthcare



Consider Your Stakeholders

- It takes an interdisciplinary team to prevent harm – this applies to any quality process
- For CDS, this may be:
  - Infection Prevention
  - Sterile processing
  - Endoscopy
  - Emergency Department
  - Nursing
  - Lab
  - Surgery
  - Regulatory
  - Performance improvement



Quality Control & Auditing

- You don’t know your opportunities if you aren’t watching your processes
- Proactive rather than reactive
- Standardize & Automate what you can
- Implement a quality-focused auditing process
  - Tiered auditing (monthly, quarterly, bi-annual, etc.)
- Audit to *YOUR* policies and procedures
- Audit your documentation
  - if it’s not documented, it didn’t happen

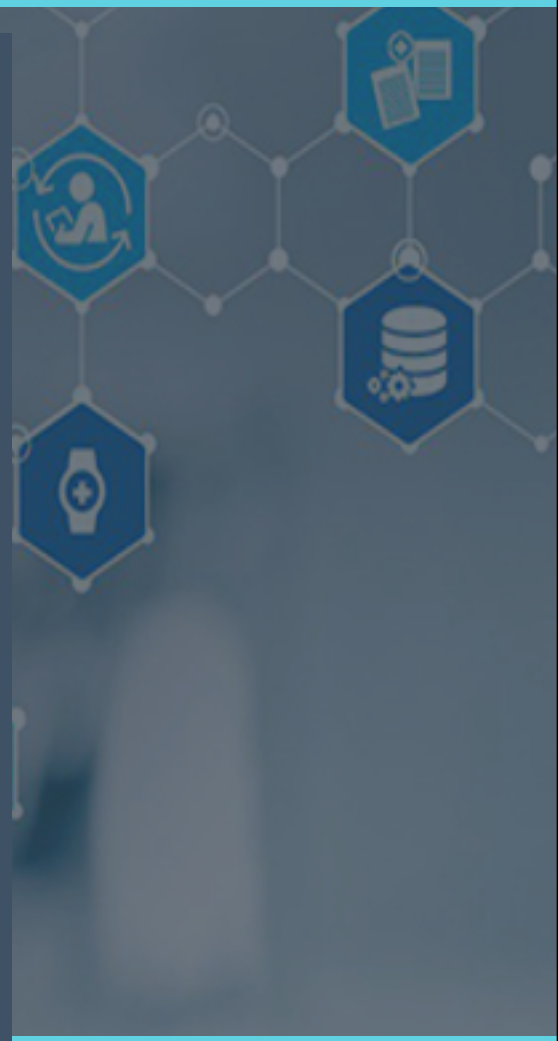
Risk Assessment

- A standard way of identifying your greatest opportunities and areas of focus
- Organizational down to the department level
- Risk assessments are "*living*" documents
  - Assessed at least annual
  - As new issues arise

Program Components	Probability of Performance- Failure				Impact (Clinical/Financial/Resources)			Infection Prevention Systems				Score	Goal
Potential Risks/Problems	High	Med	Low	Never	High	Moderate	Minimal	Poor	Fair	Good	Excellent	≥7	
	3	2	1	0	3	2	1	3	2	1	0		
Mandatory (no opting out) Local, State and Federal Regulation (add 7 to all items in this column)													
Procedures HAI's													
Surgical Site Infections													
SSI-Ortho Join Replacement													
SSI-plastic surgery													
SSI-ophthalmology													
SSI-													
SSI-													
SSI-													
Prevention Activities													
Hand Hygiene program													
Standard Precautions													
TB screening of patients													
Appropriate prophylactic antibiotic													
Appropriate OR attire													
Environment													
Medication Refrigerator Temp logs													
Sterilization monitoring													
Infection from inadequate air handling													
Positive Pressure room monitoring													
Cleaning/high level disinfection process													
Construction/Renovation Program (ICRA's)													
Regulated Waste Management Program													

Consensus Documents & Standards

- Understand what guidelines and standards are available and appropriate for your settings
- Must always be aware of updated guidelines and standards for reprocessing reusable medical equipment and using disinfectants
- Examples of standards, guidelines, and consensus documents:
  - ANSI/AAMI
  - CLSI
  - SGNA
  - APIC
  - AORN
  - CDC/HICPAC



Remain Aware of FDA Safety Notices and Recalls

- Cystoscopes
  - All HLD processes discontinued for certain scopes due to risk of infection
- Duodenoscopes
  - 2015 studies of different scopes showed between 0.3% and 8.2% of scopes had low-moderate concern organisms and between 4 and 7% had high concern organisms present after reprocessing
- Bronchoscopes
  - Between 2010 and 2015, 109 incident reports of infections and 867 reports between 2015 and 2021

Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3726

Summary

- Cleaning, disinfection, and sterilization practices are critically important to patient safety
- Poor health outcomes and infections can occur when organizations miss the mark on monitoring their CDS practices
- We can prevent error by understanding what rules and regulations, EBP, and standards apply to our organizations
- CDS can be complicated – ask your local infection prevention specialist if you are interested in learning more!

Sources

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- https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/sterilizing-practices.html#anchor_1554396578

Questions?

Thank you!

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