OBJECTIVES

At the conclusion of the training the participant will be able to:

1. Identify the differences in definitions of cleaning, disinfection and sterilization.
2. List the types of devices utilized in their center that are non-critical, critical or semi-critical.
3. Describe the methods utilized for reprocessing reusable devices.
4. State the storage requirements for the specific devices utilized in their center.

Why are we here today?

- ~ 46.5 million surgical procedures and even more invasive medical procedures—including approximately 5 million gastrointestinal endoscopies—are performed each year.
- Each procedure involves contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membranes.
Regulating Agencies

- Agencies that have regulations or standards that must be followed or subsequent fines may occur:
  - OSHA – Occupational Safety and Health Administration
  - EPA – Environmental Protection Agency
  - FDA – Food and Drug Administration
  - CMS – Centers for Medicare & Medicaid Services

Regulating Agencies

- Needlestick Safety and Prevention Act, November 6, 2000
- CMS – Centers for Medicare & Medicaid Services
- FDA – Food and Drug Administration
- EPA – Environmental Protection Agency

OSHA


Environmental Protection Agency (EPA)

[http://www.epa.gov/](http://www.epa.gov/)

Regulations for:

- *Disinfectants and Sterilants used on inanimate objects and environmental surfaces*
  - Make sure your germicides are EPA-registered and that they are being used correctly
  - Make sure your disinfectants have broad spectrum & adequate kill claims
  - Bleach is considered acceptable disinfectant, however it is not an EPA registered disinfectant and it's kill claims may not be as broad as another EPA registered
Food and Drug Administration
http://www.fda.gov/MedicalDevices/default.htm

- Issues recall notices and safety alerts
- Publishes guidance, answers questions
- Report problems
- Issues drug & device approvals and clearances.

Centers for Medicare and Medicaid Services (CMS)

- Federal agency that administers:
  - Medicare and Medicaid
  - HIPAA (Healthcare Insure Portability and Accountability Act of 1996)
- Enforces federal quality standards for various healthcare settings
Centers for Medicare and Medicaid Services (CMS)

- Oversight of Ambulatory Surgery Centers (ASCs), long term care facilities, ESRD’s, home health agencies, intermediate care facilities, mental health facilities, comprehensive outpatient rehab facilities and hospitals.
- Outlines CfC - Conditions for Coverage

CMS Regulations

- Prescribed rules
- CMS Interpretive Guidelines support implementation and enforcement of the regulations
- Regulations are described as
  - CfC - Conditions for Coverage (ASCs)
  - CoP – Conditions of Participation (Hospitals)

What is an ASC per CMS?
- Any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.
- The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the Conditions for Coverage (42 CFR 416.2-416.52)

What is Surgery per CMS?
- Procedure performed for purpose of structurally altering the human body by incision or destruction of tissues
- Also: diagnostic or therapeutic treatment (e.g. Endoscopy) of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes and needles
What is Surgery per CMS?

- Also: Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system (e.g. Pain Centers, Ophthalmology)
- New ASC Conditions for Coverage became effective May 18, 2009
  - Added a CfC on "Infection Control"

Infection Control CfC

- §416.51 consists of:
  - Condition statement
  - 2 Standards
- §416.44(a)(3) also retained

Condition

- §416.51: The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

Program Leadership

- Health care professional, qualified by training in infection control
  - Certification desirable, but not required
  - Ongoing training required to maintain competency
- ASC must designate a person to be in charge of Infection Control program’s director in writing
ASC Infection Control Challenges

- Patients in common areas
- Surgical prep, recovery rooms and ORs turned around quickly for multiple patients
- Patients entering with communicable diseases may not be identified
- Surgical site infection risks
- Patient short stay makes identifying infections associated with the ASC harder
- Requires gathering information after the patient’s discharge rather than directly

Risk Mitigation

- Other ASC HAI Prevention measures:
  - Using disinfectants and germicides per manufacturers' instructions
  - Appropriate sterilization or high-level disinfection of instruments/equipment
**PURPOSE**

- Preventing infections in patients undergoing procedures in our centers
- Provide a clean and sanitary environment
- Provide guidance on strategies to Target Zero prevent and control healthcare associated infections

**Risks Associated with Procedures Being Performed**

- **Major Risk** - the introduction of pathogens that can lead to infection.
  - **Failure** to properly disinfect or sterilize equipment carries
    - risk associated with breach of host barriers
    - risk for person-to-person transmission (e.g., hepatitis B virus) and
    - risk of transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*).

**Risks Associated with Environment**

- **High Touch Surfaces** - pose a risk because pathogens can reside and multiply if they are never physically removed or disinfectected. Personnel pick up on hands
  - **Failure** to properly disinfect or sterilize equipment carries
    - risk for employee-to-patient transmission (e.g., MDRO’s, C. difficile) and
    - Risk of transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*).
**HIERARCHY OF RESISTANCE**

- Bacterial spores (Bacillus subtilis)
- Mycobacteria (M.TB)
- Nonlipid or small viruses (polio)
- Fungi (Trichophyton spp.)
- Vegetative bacteria (Pseudomonas aeruginosa, Staph aureus)
- Lipid or medium sized viruses (Herpes simplex, Hepatitis B, HIV)

**Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants**

<table>
<thead>
<tr>
<th>Most Resistant</th>
<th>Most Susceptible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prions</td>
<td>Enveloped viruses (medium-sized)</td>
</tr>
<tr>
<td>Spores (C.difficle, B. subtilis)</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria (TB)</td>
<td></td>
</tr>
<tr>
<td>Non-Enveloped Viruses (small)</td>
<td></td>
</tr>
<tr>
<td>Fungi (Trichophyton spp)</td>
<td></td>
</tr>
<tr>
<td>Bacteria (S.aureus)</td>
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</table>
Cleaning, Disinfection & Sterilization
Principles & Practices for Healthcare Personnel

July 2008

Meredith Shellner, RN, BSN, MSA, CIC - Infection Control TMC-LW

Cleaning & Disinfection in ASCs

- Responsibility for routine cleaning and disinfection of environmental surfaces should be assigned to appropriately trained HCP.
- Cleaning procedures can be periodically monitored or assessed to ensure that they are consistently and correctly performed.
- EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare should be selected for disinfection.
- Disinfectant products should not be used as cleaners unless the label indicates the product is suitable for such use.
- Healthcare professionals should follow manufacturer’s recommendations for use of products selected for cleaning and disinfection (e.g., amount, dilution, contact time, safe use, and disposal).

CLEANING

- Removal of all foreign material inorganic and organic materials (protein) such as soil or blood and body fluids from an item by use of water, mechanical action, detergents and/or enzymatic products.
- Enzymatic cleaner/detergent
  - **Key point** > read label to determine if the product has cleaning properties

DECONTAMINATION

- Thorough cleaning is essential before high-level disinfection and sterilization
  - materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.
- **Decontamination** removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

DISINFECTION

- Elimination of many or all disease-producing microorganisms except bacterial spores, on inanimate objects
- **Key point** > Disinfectants approved for use on inanimate items/equipment are different than those used on instruments or devices
GERMICIDES

- An agent that can **kill microorganisms**, particularly pathogenic organisms ("germs").
- **Germicide** includes both antiseptics and disinfectants.
  - **Antiseptics** are germicides applied to living tissue and skin;
  - **Disinfectants** are antimicrobials applied only to inanimate objects (can harm living tissues).

DISINFECTION

- **HIGH LEVEL**...destroys all organisms with the exception of spores
- **INTERMEDIATE LEVEL**...kills MTB, vegetative bacteria, viruses, fungi (does not necessarily kill bacterial spores)
- **LOW LEVEL**...kills most bacteria, some viruses, some fungi (not reliable for killing resistant microorganisms such as tubercle bacilli or bacterial spores)

LOW LEVEL DISINFECTANTS

Non-Critical or Environmental Surfaces – Not Instruments

- Ethyl or Isopropyl alcohol (70%);
- Quaternary ammonium germicidal detergent
- Sodium Hypochlorite (pre-mixed solutions, 5.2% household bleach) [Used in special circumstances – approved by Infection Control];
- Phenolic germicidal detergent;
- Iodophor germicidal detergent;

Surface Disinfection

- **CDC Infection Prevention Checklist for Outpatient Settings**
  - Environmental Cleanliness
  - Need to have appropriate disinfecting agent
    - Staff need to be aware of product label claim and recommended **contact time** required for environmental disinfection
    - **CDC Recommends ≥ 1 minute**
Facts about environmental disinfectants:
- Clean any visible soil before use
  
Cleaning – Low & Intermediate Level Disinfection

- Apply solution with wet cloth or use a pre-saturated cloth product – do not spray the solution because of respiratory tract irritation

Cleaning – Low & Intermediate Level Disinfection

- Allow to air dry – extended contact time is essential for disinfection. Each product will be labeled with a "contact time". Your staff needs to know what this is.
STERILIZATION

- **Process** that destroys or eliminates all forms of microbial (including fungal or bacterial spores) life and is carried out in health-care facilities by physical or chemical methods.

- **Methods**: Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities.

Spaulding Approach

- **Spaulding Approach** to disinfection and sterilization of patient-care items and equipment.
- **Nature of disinfection could be understood readily if instruments and items for patient care were categorized**:
  - **Critical**
  - **Semicritical**
  - **Noncritical**

**NON-CRITICAL**

**Touches intact skin**

- **Low-level disinfection**
  - Example: stethoscopes, IV Pumps, BP cuffs, tabletops, etc.
  - **NOTE**: All equipment MUST be cleaned and disinfected between patient. Some equipment must undergo more detailed cleaning and disinfection.

  - **Germicidal Wipes (Quaternary ammonium)**
    - Many are effective against Mycobacterium tuberculosis and Hepatitis B, C & HIV.
    - Can be utilized for blood and body fluid spills, may be utilized in the O.R.
    - Those with Isopropyl alcohol decrease dry time.
SEMI-CRITICAL

**Touches mucous membranes** except dental
- Example: endoscopes, laryngoscopes, bronchoscopes, ET tubes, Respiratory therapy and anesthesia equipment
- *High-level disinfection*—sporicidal chemical; short contact
- Product classification—sterilant and/or disinfectant

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**SEMI-CRITICAL**

Some items may require only Intermediate-level disinfection
- Product classification—hospital disinfectant with label claim for tuberculocidal activity
- Example: hydrotherapy tanks, pulse oximeters, etc.

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**HIGH LEVEL DISINFECTANTS (HLD)**

For **SEMI-CRITICAL ITEMS & those that are Temperature Sensitive**
- 0.55% Ortho-Phthalaldehyde (OPA)
- Glutaraldehyde (≥ 2.0%)
- Hydrogen peroxide (HP) – 7.5%
- Peracetic acid (PA)
- HP (1.0%) and PA (0.08%)
- HP (7.5%) and PA (0.23%)

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**Glutaraldehyde & OPA**

- Different formulations & brands
- Ready to use
- Can be used manually or in an AER
  - Use Test Strips
  - Check MEC (Minimum Effective Concentration)
  - Check Temperature with each MEC Check
  - Maintain Log
- Rinse thoroughly (sterile or tap water)
- Neutralize before disposal (check State regs)
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10/29/2011 ASC Infection Prevention Training Meredith Shellner, RN, MS, CIC

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Test Strips & MEC

- Dilution of chemical occurs during routine use
- Test strips check to make sure the chemical is still able to disinfect
- Do not use Test Strips of chemical agent beyond manufacturer’s recommendation or Expiration dates
- Must keep lid tightly closed on container when not in use (Test strips and Solution)

Endoscopes

- Always wipe the outside immediately after use
- Wear appropriate PPE
- Leak Test
- Thorough cleaning, remove all valve covers
- Brush all lumens
- HLD – fill all channels, lumens, immerse
- Follow Manufacturer’s recommendations for products to use on cables & connectors
  - Rinse thoroughly, sterile v. non-sterile water
  - Flush channels with 70% IPA
  - Blow with compressed air

Disinfection – High Level Disinfection (HLD)

- Monitoring HLD solutions
  - Concentrations will dilute as wet items are placed in to soak
  - Concentrations need to be verified before each use
  - Specific product test strips/kits
  - Recommendation for QC with each bottle of strips
  - Solution needs to be discarded at the end of use life or sooner if diluted and no longer effective

- Infection Prevention should routinely assess the monitoring process.

Compliance Ratio:

- Ultrasound 2010
- JAN FEB MAR APR MAY JUN JUL AUG SEP OCT NOV DEC
- Is solution dated?
- Is solution discarded at recommended time?
- Is solution tested for efficacy daily?
- Are test strips dated when the bottle is opened?
- Are test strips discarded 90 days after bottle opened?
- Are test strips tested for efficacy when the bottle is opened?
- Is PPE available and in use when solution is poured or discarded?
- Can staff explain the process for handling an OPA spill?
- Is KemSure available in the room?
**CRITICAL Items**

- **Enters sterile tissue or vascular system**
  - Sterilization--sporicidal chemical; prolonged contact
  - Product classification--sterilant/disinfectant
  - Example: Instrumentation--scalpels, needles, hemostats, retractors, implants, endoscopic biopsy forceps, etc.

**STERILIZATION**

- **FLASH & TERMINAL - Steam**
- **Plasma Sterilization (Sterrad®)**
- **Flexible Endoscopes - Liquid (Chemical) Immersion (OPA or Peracetic Acid)**

**Physical Layout**

- Separate Decontamination from Reprocessing (Sterilization) areas (where feasible separate rooms)
- Adequate plumbing and utility
- Separate area to store scopes so they can hang freely to dry

**Decision Tree – CLEANING, DISINFECTION, STERILIZATION**

- **PPE – Staff will wear:**
  - a fluid resistant cover gown,
  - heavy-duty or Nitrile gloves,
  - hair covering including facial hair covering and
  - a mask with eye protection or a face shield to protect from splashes and sprays.
  - Jewelry will be removed.
- **Approved agents for cleaning**
  - CLEANING, Cleaning, cleaning!!
- **Appropriate agents for disinfection**
- **Appropriate agents for sterilization**
Decontaminating Instruments

- Instruments will be rinsed upon receiving and disassembled when applicable.
- Lumens are to be flushed.
- Instruments will be inspected to assure that gross organic debris has been removed.
- Instruments preferably should be cleaned utilizing an automated method.

Pre-cleaning at Point of Use

A. Wear Gloves at a minimum, & Fluid-resistant gown, as needed.
B. Separation of waste and re-usable items.
C. Remove & Dispose of Sharps in a hospital approved sharps container.
D. Remove Gross contaminates from reusable items. (rinse under running water)
E. Lumens will be flushed before and during rinse cycles.

Ultrasonics

A. May be used for delicate instruments or those with tiny lumens (e.g. eye, dental).
B. Sonic waves generate minute bubbles on the instrument surface.
C. Bubbles expand, then collapse or implode.
D. Implosion generates localized vacuum and sucks off the soil.

Manual Washing of Instruments

- All instruments are cleaned according to manufactures recommendations.
- Place items to be cleaned in sink with hospital approved detergent.
- Brushing of rough surfaces and irrigation of lumen or channels should be performed by the immersion method using cool water.
- Brushing and irrigation should occur below the water level (protects from splashing & spraying).
- Rinse with clean water twice.
Enzymatic Detergents

- Cleaning of instruments or reusable devices – always follow Manufacturer’s recommendations
- Detergents are substances capable of dislodging, removing and dispersing solid or liquid soils from a surface being cleaned
- Enzymatic detergents usually consist of a detergent base with a neutral pH to which one or more enzymes and a surfactant is added.

Flexible Gastrointestinal Endoscopes OPA

- AER (automated endoscope reprocessor) or Manual
  - Check MEC (minimum effective concentration)
  - Monitor temperature of HLD
  - Check & record temperature daily
- AER registers a minimum 25°C run for 5 minutes
- Manual 20°C for 12 minutes

Selection of Disinfecting Agent or Process

- Equipment or instruments being reprocessed
- Intended use of equipment
- Manufacturer’s recommendations
- Degree of disinfection needed (HLD v. Sterilization)
- Ability to meet requirements for safe use of the disinfecting agent (location, physical layout)
- Turnaround time

Steris System 1E

- Liquid Chemical sterilant processing system (Peracetic acid)
- Devices are wet and unwrapped
- High level disinfection
- Safe for urologic scopes
**Sterrad NX**
- Hydrogen Peroxide Gas plasma
- Low temperature
- Use on heat-stable, heat-sensitive & moisture sensitive instruments that have to be sterile (e.g. Cystoscopes in Surgery suite)
- Rapid cycle
- No fumes and no aeration required

**Mechanical Indicator**
A device built into a sterilizer that uses pre-established parameters to indicate malfunction or operational errors.

**Chemical Indicator**
- A hospital approved Internal integrators and External chemical indicator
- Specific to the type of sterilization process
- Used with each pack or tray
- Peel packs must come with an external indicator
- Appropriate color changes on external chemical indicators suggest that exposure to the sterilant has occurred
- Does not indicate sterility
  - Indicates that the item has been exposed to a sterilization agent.

Bowie Dick Test for Steam Sterilizer
monitors efficacy of air removal and steam penetration
Class V and VI Integrators

- Chemical indicator that reacts to more than one of the critical parameters (steam penetration, temperature, pressure, time)
- Provides high level of quality assurance
- Must be used with a Biological indicator
- Class VI Integrators are new and being added to AAMI Standards ST79

Biological Indicator

- Biological Indicators (Spore Checks)
- All sterilizers (Steam & Sterrad)
  - Biological testing performed daily
  - Perform when in operation,
  - Assess the efficacy of the sterilization process.
  - Use BI for every implant
- Days sterilizers are not in operation will be documented on biological testing log. (E.g. “closed” or “not in use.”)

Biological Indicator (BI)

- A biological indicator will be performed with any implantable that is processed.
  - The Surgeon (Physician) and Infection Prevention will be notified immediately in the event of a positive biological result.
  - Always make sure all other mechanical and Chemical parameters were met
  - Identify and correct errors retest (mechanical, chemical & BI), before putting back in service
- If repeat BI negative and all other parameters met then put back in service

Terminal Sterilization

- sterilization is the complete destruction of all microbial life.
- Packaged items will be sterilized according to the sterilizers written parameters.
- Follow recommendations of the manufacturer.
- Shelf Life of items sterilized is Event-Related, i.e., depends on the condition of the packaging.
**Flash (Immediate Use) Sterilization**

**AAMI Definition:**
Process designed for the steam sterilization of patient care items for immediate use

**Immediate Use - High temperature (270-275 °F)**

**TJC Definition:**
Sterilizing unwrapped instruments for 3 minutes at 270°F at 27 to 28 lbs of pressure

NOT TO BE USED to Make up for Shortages in Inventory

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**ASC Sterilization Practices**

Surveyors will utilize the following questions to assess the appropriateness of the ASC’s sterilization practices:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?

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**ASC Sterilization Practices**

6. Is the sterilizer labeled for this cycle by the manufacturer?
7. If a biological indicator is used is it labeled for use for this cycle by its manufacturer?
8. If the cycle is used frequently, is it checked regularly with a biological indicator?
9. If an ASC is properly using short sterilization cycles for wrapped/contained loads, then it should not be cited for a violation of the ASC infection control requirements.
10. Note the emphasis on the manufacturer’s instructions for use, which have been validated by the manufacturer and reviewed and cleared by FDA appropriateness.
**Packaging of Sterile Items**

- Peel Packs
  - Proper Placement of items & indicators
- Wraps (Disposable-non-reusable)
  - Indicator tape, type of wrap
- Container systems
  - Rigid Container systems, stainless steel
  - Chemical Indicators

**Preparing Items for Sterilization**

- Items must be checked for workability and cleanliness
- Only items to be terminally sterilized will be packaged
- Items will be packaged to allow contact with the sterilant (**Steam or chemical**)
- Stainless steel items must have proper lubrication done (**manual soak or automatic**)

**Quality Assurance**

- Pre-Vacuum Steam Sterilizer
  - a Bowie Dick test run Daily to assure that all air is removed from the chamber
  - Biological Indicators are run Daily to assure the cycle was able to kill all microbial life
- Mechanical Check - assures the machine is working properly.
- Check Print Out (Tape): Time, Temperature, Cycle

**Items sterilized**

- Assure the item has been packaged as to allow for the sterilant to reach all surfaces
- If a sterile item touches a non sterile item the item is no longer considered sterile.
Determining Sterility

A. If there is an expiration date, check to assure that date has not passed
B. If the package is torn the item can not be used
C. If the tape markings have been removed, notify CS

DO NOT USE

1. If the package has been compromised by liquid
2. If the package had been crushed
3. If the seal is broken
4. If the item is dirty
5. If packaged item is dropped to the floor

Sterility Assurance:

- Event-Related Sterilization – What is an Event?
  - Package integrity – torn, wet, otherwise no longer sterile
- Storage of sterile supplies
  - Right to Left; Top to Bottom; Front to Back
- Ventilation/Air change requirements

Storage:

- Store at least
  - 8-10 inches from floor so can clean underneath
  - 18 inches from fire sprinkler (ceiling)
  - Solid bottom shelf
  - Dust cover seldom-used supplies
- Closed cabinets
  - Avoid high traffic areas
  - No rubber bands
**Event-Related Sterility Assurance**

- **Event:** any of the following that causes an item to become non-sterile: usage, tears, moisture, broken seals, soil, or anything that causes doubts of sterility for any reason.

**Sterility Assurance**

- Inspect all instruments
- Instrument maintenance process
- Copies of Biological Indictors (how long)
- Record keeping
- When to notify the IP or do Follow-up
  - Positive biological (Product Recall & Repeat BI testing)
  - Failed mechanical
  - Failed chemical

**Identification**

A. Instruments will be placed in a **hospital approved rigid, sealable container** labeled with a universal biohazard symbol.
B. Perform **Hand Hygiene**
C. A **List of items** being placed in the container should accompany the container to assure tracking and that instruments are returned to the proper department.
D. **Dirty Instruments** will be **transported** to the decontamination area via a separate transportation process from the delivery of clean items.

**Returning Items for Sterilization**

- Place items into Biohazard, rigid container
- Ensure the lid is completely closed
- Place **Items list** on **top** of container
- **List number** of packs, sets or items in container
- **Initial & Date** next to contents
- **Initial & Sign** (at Bottom)
Reuse of Single Use Medical Devices (SUDS)

- Manufacturer states "Single Use only" on many products –
  - do NOT reprocess
  - Liability is incurred by your facility
- Can only be reprocessed by a 3rd party who meet FDA 510(k) status

References

- CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations 2011
- Schaefer, Melissa. Infection Control Assessment of Ambulatory Surgical Centers. JAMA, June 9, 2010—Vol 303, No. 22
- Processing/Reprocessing Medical Devices in Health Care Settings: Validation methods, U.S. Department of Health and Human Services, Food and Drug Administration, May 2, 2011

QUESTIONS?