Infection Control Basics – Key Practices that are a Must

Educational Webinar

June 21, 2017

Pamela Roark-Parlier, MA, MSN, RN
Joint Commission Clinical Surveyor, Ambulatory Care Program
Webinar Objectives:

- Describe the most challenging infection control compliance issues related to sterilization and high-level disinfection
- Understand the basics of proper sterilization and high-level disinfection practices
- Identify examples and strategies to ensure compliance
The Joint Commission’s Mission and Vision

**Mission:** To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

**Vision:** All people always experience the safest, highest quality, best-value health care across all settings.
2016 Top Challenging Ambulatory Standards for Health Centers
## 2016 Top Challenging Standards/Elements of Performance for HRSA Funded Ambulatory Program Standards

<table>
<thead>
<tr>
<th>Ambulatory Program Standards</th>
<th>EP</th>
<th>Scored</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC.02.02.01: The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. (See also EC.02.04.03, EP 4)</td>
<td>2</td>
<td>72%</td>
</tr>
<tr>
<td>EC.02.04.03: The organization conducts performance testing of and maintains all sterilizers. These activities are documented. (See also IC.02.02.01, EP 2)</td>
<td>4</td>
<td>45%</td>
</tr>
<tr>
<td>MM.03.01.03: Emergency medications and their associated supplies are readily accessible. (See also PC.03.01.01, EP 8)</td>
<td>2</td>
<td>42%</td>
</tr>
<tr>
<td>MM.03.01.01: The organization stores medications according to the manufacturers' recommendations. Note: This element of performance is also applicable to sample medications.</td>
<td>2</td>
<td>40%</td>
</tr>
<tr>
<td>MM.01.02.01: The organization takes action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.</td>
<td>2</td>
<td>34%</td>
</tr>
</tbody>
</table>
## 2016 Top Challenging Standards/Elements of Performance for HRSA Funded Ambulatory Program Standards

<table>
<thead>
<tr>
<th>Ambulatory Program Standards</th>
<th>EP</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC.02.02.01: The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals.</td>
<td>5</td>
<td>33%</td>
</tr>
<tr>
<td>EC.04.01.01: Every 12 months, the organization evaluates each environment of care management plan, including a review of the plan’s objectives, scope, performance, and effectiveness. (See also EC.01.01.01, EPs 3-8; EC.04.01.03, EP 1)</td>
<td>15</td>
<td>31%</td>
</tr>
<tr>
<td>WT.03.01.01: Competency for waived testing is assessed using at least two of the following methods per person per test: Performance of a test on a blind specimen; Periodic observation of routine work by the supervisor or qualified designee; Monitoring of each user's quality control performance; Use of a written test specific to the test assessed.</td>
<td>5</td>
<td>30%</td>
</tr>
<tr>
<td>MM.03.01.01: The organization prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation. Note: This element of performance is also applicable to sample medications.</td>
<td>6</td>
<td>28%</td>
</tr>
<tr>
<td>IC.01.03.01: The organization identifies infection risks based on the following: Its geographic location, community, and population served.</td>
<td>1</td>
<td>24%</td>
</tr>
</tbody>
</table>
IC.01.03.01, EP1

The organization identifies infection risks based on the following: its geographic location, community and population served.

- Failure to identify any specific or potentially increased infectious risks for locations or patient populations with unique characteristics
The Basics: Infection Control Risk Assessment

Geographic location, community and population served – query your local Health Department for surveillance data.

– Review population and community demographics and characteristics
Example of Public Health Department Query
Example of Public Health Department Query

### Tuberculosis Morbidity, Florida 2016

In 2016, 639 tuberculosis cases were reported in Florida. This represents a 6.1% increase in cases since 2015 (602), however cases have declined by 23% since 2010 (833).

#### Gender
- Men: 59% (379/639)
- Women: 41% (260/639)

#### Nationality
- U.S. Born: 38% (242/639)
- Foreign-Born: 62% (397/639)

#### Age Group*
- 0-4: 2% (13/639)
- 5-14: 2% (10/639)
- 15-24: 7% (42/639)
- 25-44: 30% (194/639)
- 45-64: 35% (222/639)
- 65 and over: 25% (158/639)

#### Ethnicity/Race
- Non-Hispanic: 74% (472/639)
Example of Public Health Department Query

Florida Influenza Surveillance Report Archive

Historical reports are available dating back to the 2001-02 influenza season.

The flu season typically runs from October to May. To better contextualize the data presented in these reports, we have grouped them by season rather than calendar year.

Florida Flu Review Archive

The most recent Florida Flu Review and summary is available on the Influenza webpage.

Make a selection below to view previous Florida Flu Reviews for that season.

- 2016/2017
- 2015/2016
- 2014/2015
- 2013/2014
- 2012/2013
- 2011/2012
- 2010/2011
- 2009/2010
- 2008/2009
- 2007/2008
- 2006/2007
- 2005/2006
- 2004/2005
- 2003/2004
- 2002/2003

Contact the Florida Department of Health

- Phone: 850-245-4444
- Email: health@fhealth.gov
- Mailing Address: Florida Department of Health, 4052 Bald Cypress Way, Tallahassee, FL 32399
The Basics: Infection Control Risk Assessment

- Review patient demographics of patients seeking care at clinic
  - Unique populations – schools, homeless shelters, rural areas, prisons, jails
  - Health characteristics – elderly, immunocompromised, Co-morbidities

- Care, treatment and services provided

- Analysis of Infection Control and surveillance data
Example of Risk Assessment Grid

Table 1. Risk Assessment Grids

Risk assessment grids may be used to evaluate and prioritize an organization’s IC risks. By rating the probability, potential severity, response, and preparedness of an organization and tallying the ratings for each risk, organizations can effectively identify their priority risks.

<table>
<thead>
<tr>
<th>Event</th>
<th>Probability of Event Occurrence</th>
<th>Potential Severity/Risk Level of Failure</th>
<th>Organizational Response</th>
<th>Current State of Preparedness</th>
<th>Risk Level For Org</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Preparedness</td>
<td>H 3</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Water Supply Unavailable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Patient Care Supplies Unavailable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>9</td>
</tr>
<tr>
<td>Evacuation Required</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>High Risk Procedures and Processes</td>
<td>H 3</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Hand Hygiene Compliance &gt;80%</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Endoscope Contamination</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Unauthorized Use of SUDs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Inadequate Cleaning/Disinfection of Patient Care Equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>5</td>
</tr>
<tr>
<td>Inappropriate Use of Isolation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>10</td>
</tr>
</tbody>
</table>

Rating key: N = no risk; L = low risk; M = medium risk; H = high risk
Compliance Issues: Infection Control

- IC.01.03.01, EP5

The organization prioritizes the identified risks for acquiring and transmitting infections. These prioritized risks are documented.

- No documentation of prioritized identified risks for acquiring and transmitting infections
Example of Determining Prioritized Risks

Table 1. Risk Assessment Grids

Risk assessment grids may be used to evaluate and prioritize an organization’s IC risks. By rating the probability, potential severity, response, and preparedness of an organization and tallying the ratings for each risk, organizations can effectively identify their priority risks.

<table>
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<th>Organizational Response</th>
<th>Current State of Preparedness</th>
<th>Risk Level for Org</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency preparedness</td>
<td>H 3</td>
<td>Life Threatening 3</td>
<td>Temp Harm 1</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Water Supply Unavailable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Patient Care Supplies Unavailable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>9</td>
</tr>
<tr>
<td>Evacuation Required</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>High Risk Procedures and Processes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand Hygiene Compliance ≥90%</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>8</td>
</tr>
<tr>
<td>Endoscope Contamination</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Unauthorized Use of SUDs</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Inadequate Cleaning/Disinfection of Patient Care Equipment</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Inappropriate use of Isolation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>5</td>
</tr>
<tr>
<td>Inappropriate use of Isolation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>10</td>
</tr>
</tbody>
</table>

Rating key: N = no risk; L = low risk; M = medium risk; H = high risk
The Basics: Infection Control Goals

IC.01.04.01

Based on identified risks, the organization sets goals to minimize the possibility of transmitting infections. Goals include the following:

- Addressing Prioritized Risks (EP1)
  - Limiting unprotected exposure to pathogens (EP2)
  - Limiting the transmission of infections associated with procedures (EP3)
  - Limiting the transmission of infections associated with medical equipment, devices and supplies (EP4)
  - Improving compliance with hand hygiene compliance (EP5)
## Example of Infection Control Goals

<table>
<thead>
<tr>
<th>Goals</th>
<th>Objectives</th>
<th>Actions</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Achieve 95% compliance with hand hygiene</td>
<td>Consistently meet observational hand hygiene audit compliance of 95% or better</td>
<td>• Hand Hygiene Campaign has been approved by the ASC Governing Board&lt;br&gt;• A physician champion has been named&lt;br&gt;• Hand sanitizers installed on anesthesia carts</td>
<td>Compliance by all HCWs and sustainability of improvements</td>
</tr>
<tr>
<td>2. Reduce surgical site infections by 10%</td>
<td>Prevent surgical site infections by:&lt;br&gt;a. Using the CDC SSI bundle&lt;br&gt;b. Audit surgical services for continuous compliance with antibiotic prophylactic guidelines for surgical procedures&lt;br&gt;c. Audit compliance with eligible surgical patients receiving appropriate prophylactic antibiotics within one hour prior to surgical incision time&lt;br&gt;d. All patients will have a preoperative bath with a CHG product</td>
<td>• Rates continue to be monitored and processes audited&lt;br&gt;• Education was provided to the ASC staff to improve compliance with SSI bundle&lt;br&gt;• CHG preoperative bedside baths were implemented pre-operatively</td>
<td>• Difficulty obtaining prophylactic ATB orders in time&lt;br&gt;• Not able to provide CHG pre-operative baths to all patients due to time constraints</td>
</tr>
<tr>
<td>3. Increase ASC Influenza Vaccination Rates to 90%</td>
<td>Increase employee, medical staff, volunteer, and all HCP influenza vaccination rates</td>
<td>• Offer free vaccine to all employees during immunization clinic&lt;br&gt;• Provide employees with a list of times and locations where they can receive influenza immunizations</td>
<td>Difficult to schedule clinic when everyone is available</td>
</tr>
</tbody>
</table>
Risk Assessment Process

1. Identify Risks
2. Create Goals
3. Develop & Implement IC Plan
4. Evaluate Plan

The Joint Commission
Accreditation
Ambulatory Care
Compliance Issues: Infection Control

IC.01.05.01 EP1

When developing infection prevention and control activities, the organization uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus.

- No adherence or use of evidence-based guidelines specific to sterilization
- No adherence or use of evidence-based guidelines specific to high level disinfection
The Basics: Evidence-Based Guidelines

- Must review and select evidence-based guideline(s) for your Infection Control Program
- Once selected, ensure policies and procedures are based on these guidelines
- Have readily available as a resource for staff and instrument processing personnel
The Basics: Evidence-Based Guidelines

- 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities
- ANSI/AAMI ST58:2013 Chemical Sterilization and high-level disinfection in healthcare facilities
- ANSI AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities
The Basics: Evidence-Based Guidelines

- 2015 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes
- 2016 AORN Recommended Practices for Perioperative Nursing – Sterilization and Disinfection
  - Disinfection – High-level
  - Flexible Endoscopes – Cleaning and Processing
Example of Guideline


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

\textsuperscript{1}Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

\textsuperscript{2}Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030
Example of Guideline
Example of Guideline
Compliance Issues: Infection Control

- IC.02.02.01, EP2

The organization implements infection prevention and control activities when doing the following: **Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.**
The Basics: Infection Control Tracer

- Tracer methodology is used to determine compliance with this standard
- Follow a device/instrument from point of use to storage
- Observe point-of-use cleaning, transport, cleaning, packaging, sterilization and storage
The Basics: Infection Control Tracer

- Point-of-Use
- Transport
- Storage
- Cleaning
- Inspect
- Sterilization
- Prep & Pack

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Compliance Issues: Infection Control

IC.02.02.01, EP2

The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- No manufacturer instructions for use utilized or available for instruments sterilized
- No manufacturer instructions for use utilized or available for items being high level disinfected, i.e. vaginal ultrasound probes
- Manufacturer instructions for use not being followed for use of enzymatic cleaner
- Manufacturer instructions for use not being followed for instruments, probes
The Basics: Infection Control
Instrument Tracer

Surgical Instruments

- Obtain manufacturer Instructions for Use (IFU)
- Highlight cleaning and disinfection instructions
  ➢ Have readily available for processing staff
- Surveyor will first review these to assess compliance with IFU
- If these are not available, unable to determine compliance
Example of Instrument IFU

Instructions For Use

- Apex Locator, Mark-VII(TM)
- Bipolar Forceps
- Bone Mill Set IFU
- Coniula, Endo Biopsy SoftFlax(TM) and FirmFlax(TM)
- Care and Handling of Dental and Endodontic Devices
- Care and Handling of Pedgatt Instruments
- Care and Handling of Surgical and Dental Instruments
- Cassette
- Catheters, Female and Catheter-Dilators, Walther
- Cervical Dilator Set, Reusable
- Cervical Dilators, Disposable
- Chiropractic Mallet IFU
- Collagen Membrane, HeiMend
- Collagen Membrane, HeiMend Advanced
- Collagen Wound Dressing, HeiTape, HeiCote, HeiPlug
- Contra Angle, Ball-Bearing Spring Latch
- Contra Angle, FG
- Contra Angle, U, 75-12
- Contra Angle, U, 75-15
- CryoSolutions Cryosurgical Unit
Example of Instrument IFU

Integra Miltex
Care and Handling of Surgical and Dental Instruments
Directions for Use / English

**Rx only**

**INDICATIONS FOR USE**
Surgical and dental instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, piercing, retracting, locating, aspirating, suctioning, or ligating. Surgical instruments may also be used to facilitate the insertion of surgical implants.

**CONTRAINDICATIONS**
Instruments should not be used for anything other than intended use.

**WARNING**
If any device is used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed after exposure as the instruments have not been validated to withstand the chemical and thermal exposure recommended to eradicate prions.

Consult individual national infection control/prevention protocols for specific guidance regarding processing medical devices with suspected exposure to CJD.

**PRECAUTIONS**
- Integra Miltex Instruments are supplied non-sterile, unless otherwise noted and must be cleaned, lubricated, and sterilized prior to use according to hospital protocol and procedures outlined in this document.
- Inappropriate use of instruments may result in patient injury, damaged or broken instruments.
- Proper cleaning, handling, sterilization and standard machine maintenance (such as sharpening, if applicable) will ensure that the instruments perform as intended and will extend their useful life.
- Delicate surgical instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization.
- Do not use dry heat sterilization or expose to plastics or petroleum-based products.
- Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.
- Remnants and bone cutting forces should only be used to cut bone, never wire or pin. Do not twist or apply excessive stress during use.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.
- Instruments manufactured from different metals or with special coating, should be processed separately to avoid electrolytic action between different metals.
- Before use, inspect the instruments for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts.
- Damaged or defective instruments should not be used or processed.
- Suture needles are designed for single use and should not be reprocessed. Follow sharps safety guidelines for point of use disposal.

**DECONTAMINATION AND STERILIZATION PROCEDURES**
Personnel should follow internal guidelines as recommended in your hospital’s guidelines. If you have any questions about the sterilization process, please contact your local sterilization facility.

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Vacuum Steam (Pre-vacuum)</td>
<td>270°F (132°C)</td>
<td>1 minute minimum</td>
<td>N/A</td>
</tr>
<tr>
<td>Unwrapped in containers</td>
<td>270°F (132°C)</td>
<td>4 minutes minimum</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Graphite Steam</td>
<td>395°F (202°C)</td>
<td>45 minutes</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>

独立实验室测试根据ISO 11607，验证了以下消毒参数。

**4. STERILIZATION**
After following decontamination recommendations, reusable instruments are ready for sterilization.

- See ANSI/AAMI ST79.
- AAMI standards recommend that sterilizer manufacturer’s written instructions for cycle parameters should also be followed. Medical device manufacturer’s exposure times to sterilization temperature may need to be longer than minimum indicated by sterilizer manufacturer but must never be shorter. It is the responsibility of the user to establish whether sterilizer meets these minimum recommendations.
- Instruments may be packaged in rigid containers, or packaging certified for use in sterilization. Packaging should ensure stability of instruments until opened for use at the sterile field and permit removal of contents without contamination.
- Recommended steam sterilization parameters to achieve Sterility Assurance Level (SAL) of 10^-6.
Example of IFU for Ultrasound Probe

GE Healthcare

GE Transducer Cleaning and Disinfection Guidelines

GE ultrasound transducers are designed for reliability and durability. By following the proper care and handling procedures, you can help maximize transducer performance and product life.
The Basics: Infection Control Tracer

Detergents, Enzymatics

- Obtain manufacturer Instructions for Use (IFU)
- Develop step by step policy based on IFU
- Surveyor will first review these to assess compliance with IFU
Example of IFU for Enzymatic

- Read IFU on container
- Ensure proper dilution with actual measurements
- Ensure proper temperature
- Ensure proper soak time
Compliance Issues: Infection Control

- **IC.02.02.01, EP2**

The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- No pre-cleaning of surgical instruments at point-of-use as per evidence-based guidelines
- Instruments not kept moist during transport from point of care to decontamination area
The Basics: Infection Control Tracer

- Instrument **point-of-use** cleaning described in instrument IFU and evidence-based guidelines

- Failure to adequately clean results in higher bioburden – decreases sterilization efficiency
  - Clean/wipe gross debris with moist cloth at point of use
  - Prevents instruments from drying, instruments kept moist until they are cleaned
The Basics: Infection Control Tracer

- Proper **transport** of instruments from point of use to cleaning area
  - Transport in rigid containers marked biohazardous
Compliance Issues: Infection Control

IC.02.02.01, EP2
The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- Failure to provide continuous flow from dirty to clean in sterilization process to reduce risk of cross contamination
- Staff performed hand hygiene in same sink where instruments were decontaminated
- No space allocated as “clean” area for packaging
- Clean supplies stored in “dirty” area
- Sterilization room included laboratory activities
The Basics: Infection Control Tracer

- Workflow dirty to clean – one direction
- Areas separated by walls or partition
- Clear delineation between dirty and clean
- Sink used ONLY for cleaning of instruments
The Basics: Infection Control Tracer

- Cleaning of instruments per IFU
- Enzymatic used per IFU
- Proper use of brushes – single use or at least disinfected daily
- Instruments rinsed per IFU – tap water? Sterile water? Distilled water?
Compliance Issues: Infection Control

IC.02.02.01, EP2

The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- Wet instruments placed in paper-plastic peel pouches for sterilization
- Hinged instruments in the closed position
- Several stored paper-plastic peel pouches observed to be punctured
- Chemical indicators (CIs) not visible on all packaging
- No internal chemical indicators (CI) placed in wrapped cassettes as per IFU
The Basics: Infection Control Tracer

- Instruments allowed to dry prior to packaging
- Paper-plastic peel pouches used per IFU
- If double pouched – use validated by manufacturer
- If double pouched – inner pouch not folded, fits in outer pouch
The Basics: Infection Control Tracer

- Hinged instruments in the open position
- Scissors in the open position
- Internal and external chemical indicators (CI) used for all packages as indicated
- Packages labeled properly to ensure ability to track instruments to patient
Compliance Issues: Infection Control

IC.02.02.01, EP2

The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- Physical monitoring parameters not being recorded
- Not following recommended sterilizer cycle temperatures or times per IFUs or evidence based guidelines
- Sterilization documentation lacked physical monitoring (temperature, time), load number, and date per evidence based guidelines
- No documentation of physical and chemical quality controls for each load
The Basics: Infection Control Tracer

- Follow manufacturer IFUs for determining proper sterilization parameters (Mechanical/Physical Indicator)
- Document sterilization parameters for each load (temperature, time)
# Example Sterilization IFU

## Zimmer

### Table 3. Recommended Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Minimum Temperature</th>
<th>Pressure</th>
<th>7 Minimum Exposure Time</th>
<th>11 Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 UK Prevacuum/</td>
<td>134°C 273°F</td>
<td>3 bar 28.5 psi</td>
<td>3 min</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Pulsating Vacuum</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 Prevacuum/</td>
<td>132°C 270°F</td>
<td>1.86 bar 27 psi</td>
<td>4 min</td>
<td></td>
</tr>
<tr>
<td>Pulsating Vacuum</td>
<td></td>
<td></td>
<td></td>
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<td>3 bar 28.5 psi</td>
<td>18 min</td>
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<td>Pulsating Vacuum</td>
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<td>5 Prevacuum/</td>
<td>132°C 270°F</td>
<td>1.86 bar 27 psi</td>
<td>8 min</td>
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<td>Displacement</td>
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<td>not practical.</td>
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</table>

10 Flash (unwrapped) sterilization by exposure at 132°C / 270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled.
Example of Load Documentation

- Use sterilizer print out to document parameters met for each load
- Forms/envelopes available to document date, load number, load contents, sterilization parameters and technician initials
Compliance Issues: Infection Control

IC.02.02.01, EP2
The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- Biological indicators not used consistently on a weekly basis
- Not following Biological Indicator IFUs
- Instruments released before Biological Indicator read/resulted
- Biological Indicators performed weekly and sent out, however, results were only reported quarterly to organization
- Biological Indicator testing only had date of read, no time
The Basics: Infection Control

Tracer

- **Biological Indicator** is only quality control that directly monitors the lethality of the sterilization process
- Follow manufacturer IFUs for Biological Indicator used
  - Run with full load or empty chamber?
  - Incubate for prescribed amount of time
- Document results of BI and Control
- If mailed out, must have tracking system if load released prior to result
Compliance Issues: Infection Control

IC.02.02.01, EP2

The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection (HLD) and sterilization of medical equipment, devices, and supplies.

- Performing low-level disinfection with no high-level disinfectant utilized for vaginal ultrasound probe reprocessing
- No adherence or use of evidence-based guidelines specific to HLD of intracavitary probes
- No documentation of HLD temperature or immersion time per IFU or evidence based guidelines
- Failure to perform initial disinfection with recommended product per IFU
The Basics: Infection Control

Instrument Tracer

- Instruments requiring HLD
  - Obtain manufacturer Instructions for Use (IFU)
  - Highlight cleaning and disinfection instructions
  - Surveyor will first review these to assess compliance with IFU
  - If these are not available, unable to determine compliance
Example of HLD

- Ensure proper testing of HLD prior to use
- Document new discard date once opened
- Ensure and document proper soak time and temperature
Example of IFU for HLD
Example of HLD
Example of IFU for HLD

**trophon®**

**Sonex-HL®**

ONLY FOR USE WITH THE TROPHON® EPR

Distributed in US by:
Nanosonics, Inc.
11793 Technology Lane
Fishers, IN 46038, USA
support@nanosonics.us

Distributed in Canada by:
Hansamed Ltd.
Mississauga, Ontario
Canada, L6N 8G4
www.hansamed.net

USA/Canada Customer Support:
1-844-876-7466

Manufactured for:
Nanosonics Limited
14 Mars Road, Lane Cove
NSW 2066, Australia
+61 2 8063 1600
info@nanosonics.com.au

www.nanosonics.us

MADE IN AUSTRALIA

REF N0037-NNA

EN Instructions for Use
Sonex-HL®

Single use disinfectant delivery cartridge, containing multiple doses of disinfectant. The following must be read in conjunction with the trophon EPR User Manual. This cartridge is specifically designed for use with the trophon EPR to deliver the correct dosage of disinfectant to ensure high level disinfection.

Each cartridge contains 80mL of 35% w/w hydrogen peroxide solution. Use of disinfectants with differing composition or concentration to that specified may result in damage to the device, probe and/or reduced effectiveness of the disinfection process.

1. **Warnings** (Refer to the Safety Data Sheet for more information)
   **IMPORTANT:** Cartridges are pierced at the top and on the side near the bottom upon insertion of a new cartridge into the device. A small amount of disinfectant may remain in the cartridge, even when it has been fully used. Follow the instructions carefully to avoid injury.
   - Always wear disposable gloves while handling disinfectant cartridges.
   - Avoid contact with eyes and skin.
   - Do not manually pierce the cartridge.
   - Do not attempt to open or use a damaged or distorted cartridge.
   - Do not attempt to refill or reprocess the empty cartridge after removal from trophon EPR. This could lead to personnel injury and/or equipment/device malfunction or damage.
   - Strong Oxidizer: Contact with other material may cause a fire.
   - Corrosive: Harmful if swallowed or inhaled. May cause eye and skin burns. Prolonged or repeated skin contact may cause dermatitis.

2. **Emergency Guidelines**
   - Spillage: Always wear personal protective equipment. Turn OFF the device at the power switch and at the mains power switch. Dilute with plenty of water and discharge according to Occupational Health and Safety Guidelines for your institution.
   - Eye contact: Rinse immediately with copious amounts of cold water, also under the eyelids, for at least 15 minutes. Do NOT rub or keep eyes closed.
   - Skin contact: Flush skin with copious amounts of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Consult a physician if irritation persists.
   - Ingestion: Do NOT induce vomiting. If victim is conscious and alert, rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Call a poison control centre.
   - Inhalation: Remove person to fresh air. If symptoms persist, call a physician.

L00079-WEB 3.0 01/2019
The Basics: Infection Control

Instrument Tracer

- Clean instruments/probe per IFU
- High Level Disinfect instrument/probe per IFU
- Document process to include date, load, disinfection parameters (time, temperature) and technician initials
- Store instrument/probe per IFU and evidence based guidelines
Compliance Issues: Infection Control

EC.02.04,03

The organization inspects, tests, and maintains medical equipment, and maintains all sterilizers.

- Sterilizer cleaning not conducted as per manufacturer instructions for use
- Staff unable to access or retrieve sterilizer manufacturer user manual
- The sterilizer pressure relief value not tested monthly as required
- Daily and Monthly maintenance not being performed
- Lack of or inconsistent documentation of regular maintenance of sterilizer(s)
The Basics: Infection Control Tracer

- Obtain sterilizer user manual
- Review and highlight daily, weekly, monthly, quarterly, annual maintenance requirements
- Establish policy and procedure based on requirements
- Determine who performs these tasks – staff versus biomedical technician
- Develop log to document routine maintenance and testing
# Example of Sterilizer Maintenance Requirements

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<td>Typical Alarm Printout</td>
<td>12-2</td>
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</table>
Example of Sterilizer Maintenance Requirements

11.3 Weekly Maintenance

11.3.1 Clean Chamber

**WARNING - FALL HAZARD:** To prevent falls, keep floors dry by immediately wiping up any spilled liquids or condensation in sterilizer loading and unloading areas.

**WARNING - BURN HAZARD:** Allow sterilizer to cool to room temperature before performing any cleaning or maintenance procedures.

**IMPORTANT:** The entire chamber should be wiped down and rinsed following any spills or other soiling.

1. If applicable, the shelf assembly must be removed before cleaning the chamber.

   - **Single Door**
     a. Remove shelves from rack.
     b. Use a 1/4" hex wrench to loosen (but not remove) the set screws at the front of the rack assembly.
     c. Remove the rack assembly from the chamber.

   - **Double Door**
     a. Remove shelves from rack.
     b. Use a 1/4" hex wrench to loosen (but not remove) the set screws at each end of the rack assembly.
     c. Remove the rack assembly from the chamber.

**IMPORTANT:** Chamber must be at room temperature, sterilizer off all night, before washing.

2. Wash the inside of the chamber and shelf assembly (plus any other loading equipment) with a mild detergent solution such as STERIS Liqui-Jel® or current STERIS equivalent. (Contact your local STERIS representative.)
Compliance Issues: Infection Control

HR 01.02.01 EP1

The organization defines staff qualifications specific to their job responsibilities. (See also IC.01.01.01, EP 3) Note: Qualifications for infection control may be met through ongoing education, training, experience, and/or certification (such as that offered by the Certification Board for Infection Control).

- The job description for the Infection Control Practitioner lacked qualifications, such as specific infection prevention control education and training requirements
- Lacked evidence of relevant infection control responsibilities
- Lacked delineation of specific job competencies for the role Staff unable to access or retrieve sterilizer manufacturer user manual
The Basics: Infection Control Practitioner Job Description

- Develop Job Description for IC Practitioner that includes role and responsibilities
- Include job qualifications
  - Education
  - Training specific to Infection Control
  - Training specific to job responsibilities
    - Oversight of Instrument Processing and high level disinfection
Example Job Description

Ambulatory Surgery Infection Control Preventionist-17004784

Description

Role Purpose:
The Ambulatory Surgical Infection Control Preventionist coordinates and implements the infection control program for the Ambulatory Surgery Centers (ASCs) including preventive, educational and administrative measures to ensure high quality patient care and employee safety.

Responsibilities:

Infection Control Program Management:
1. Serves as a resource for the ASCs, its patients and the community regarding infection control and prevention.
2. Establishes, implements, maintains, annually reviews and updates written infection control and prevention policies and procedures (i.e. Exposure Control Plan, Bloodborne Pathogens Standard, etc.).
3. Responsible for design and production of the ASC Infection Control Manual.
4. Responsible for design and production of the ASC Infection Control Manual.
5. Uses formal and informal observations and review mechanisms to assess the effectiveness of the Infection Control program and staff awareness of their role in ensuring and maintaining a safe environment.
6. Collaborates with, and acts as liaison to appropriate local and state health departments; promotes and maintains collegial relationships with other ambulatory care providers, hospitals, community agencies, etc.
7. Evaluates the adequacy of facilities by completing periodic on-site inspections to include supplies and equipment in terms of patient and staff needs as they relate to Infection Control.

Staff Training and Education:
1. Provides ongoing educational initiatives in infection control and prevention to the ASC staff.
2. Collaborates with Nurse Educator to determine appropriate competencies related to infection control.
3. Outlines the required yearly staff training related to infection control.
4. Oversees new employee orientation related to Infection Control for all new staff.
5. Reviews significant exposures periodically to monitor for trends or training needed.

Regulatory Compliance:
1. Acts as a liaison with local and state health departments, as well as other Infection Control Specialists in the community.
2. Assists in maintaining compliance with relevant regulatory and accreditation requirements for the ASC (i.e. The Joint Commission, CMS, APIC, etc.).

Quality Assurance:
1. Performs monthly infection surveillance activities.
2. Reports significant findings to ASC management and the QA Committee.
3. Participates in quality assurance activities for the ASCs as needed.
4. Participates and sits on Committees as appropriate.

Qualifications

Required:
1. Bachelor’s degree in relevant field (i.e. nursing, microbiology, etc.).
2. 5 years relevant experience.
3. Interest and involvement in infection control.
4. Demonstrates flexibility to meet department needs on short notice.
5. Adapts easily to the workflow of the different departments
6. Ability to travel to other sites as needed.

Preferred:
1. Master’s degree.
2. Preferred degrees in nursing, microbiology or public health.
Compliance Issues: Infection Control

HR 01.02.05 EP 3

The organization verifies and documents that the applicant has the education and experience required by the job responsibilities.

- The Infection Control Preventionist lacked evidence of background, experience or knowledge related specifically to instrument processing, sterilization and high level disinfection.
The Basics: Infection Control Practitioner

Person identified to assume role and responsibilities of Infection Control Practitioner must have the education and experience

- Many resources available for education and training
  - APIC, AORN, others…
  - Sterilization and HLD: 3M University; Steris University
Compliance Issues: Infection Control

HR 01.02.05

EP 5 Staff competence is initially assessed and documented as part of orientation

EP 6 Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.

- Lack of initial or on-going, documented frontline staff competency and training specific to sterilization processes
- Lack of initial or on-going, documented frontline staff competency and training specific to HLD processes
- No documentation of competency related to sterilization
- Competency of staff for instrument processing limited to check off box titled “use of autoclave”
The Basics: Competency Assessment

- Develop competency assessment tool specific to job responsibilities
- Develop competencies for sterilization and/or high level disinfection based on evidence based guidelines and IFUs
- Assess competency at time of orientation
- Assess competency at frequency determined by leadership but no less than every 3 years
# Example Competency Assessment Checklist

**Name:**

**Facility:**

**Date:**

**Certification Due Date:**

**Department:**

**Certifier Name:**

**Manager:**

**Certifier Signature:**

<table>
<thead>
<tr>
<th>CRITICAL ELEMENTS MUST MEET ALL ELEMENTS</th>
<th>MET</th>
<th>NOT MET</th>
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## Pre-Cleaning:

1. Applies appropriate PPE for type of precleaning.
2. Cleanser wipes gross debris with wet cloth at point of use or immerses in approved enzymatic cleaner per manufacturer's directions.
   - Discards precleaning solution after use.
3. Transports to cleaning area in approved container.

## Cleaning:

1. Washes hands.
2. Applies personal protective equipment (PPE): eyewear and mask or face shield, impervious long-sleeve gown & gloves.
3. Pre-rinses instruments under cold running water to remove any visible soil.
4. Grabs basket or utilizes mechanical device to lift not individually wrapped instruments.
5. Places instruments in appropriate container with manufacturer approved enzymatic detergent.
   - Leaves hinged instruments in open position and disassembles those with removable parts.
   - Label(s) basin with product name and date mixed. (Secondary label per DHHS Hazardous Communication Policy.)
   - Instruments are cleaned per manufacturer's guidelines.
6. Scrubs all surfaces with scrub brush, pipe cleaner, or other cleaning tools, paying special attention to crevices, edges, and hidden parts of instruments. (Secondary label per DHHS Hazardous Communication Policy.)
   - Must be scrubbed while submerged in enzymatic cleaner to prevent aerosolization of BSI.
   - Brosches and cleaning tools are replaced when needed.
   - No metal brushes are used.
   - Discards enzymatic detergent after use.
7. Re-rinses thoroughly in cool tap water.
8. If ultrasonic machine is used:
   - Runs cycle per manufacturer's recommendations.
   - Removes instruments from tank when cycle complete and inns in tap or distilled water per manufacturer's guidelines.
   - Airs to air dry completely. Travels, etc. will leave lint.

## Disinfecting instruments:

1. After cleaning, places hinged instruments and those with movable parts in a soak solution (per manufacturer's guidelines).
2. If new solution, marks container with contents, date of preparation, expiration date 14 days post disinfectant and soak. (Secondary label per DHHS Hazardous Communication Policy.)
3. Disinfectant solution has properly been diluted, is gray tint or has reached expiration date. Soaking times should be recorded and disinfectant solution discarded when it is 2 weeks past the date of preparation.
4. Instruments are thoroughly rinsed per manufacturer's guidelines.

## Inspecting:

1. Checks instruments for the following prior to packaging:
   - Hinged instruments for ease of opening and alignment of joints and teeth.
   - Sharp or semi-sharp instruments for sharpness.
   - All instruments for cracks, chips, sharp edges or worn spots.
   - Markable instruments for dents and bends.
2. Removes from source ANY instruments with any defects and barns into appropriate person for repair.

## Packaging for Sterilization:

1. Heaters instruments are always inserted or placed in the wrap first.
2. Curved tips are always pointed in the same direction.
3. Sharp tips can be covered w/ gauze or special tip covers for protection.
4. Capped or concave instruments are positioned to avoid water/condensation collection.

## Wrapping:

1. Does only the one-wrap step in appropriate size for contents. DO NOT CUT WRAP TO SIZE.
2. Places the steam indicator in the center of pack. One end should be visible when pack opened.
3. All instruments must be in the open position or disassembled to their smallest parts.
4. Separates the metal boxes/baskets with appropriate material i.e. gauze, towel to prevent condensation and expose all surfaces to sterilization.
5. Secures with a minimum of 3 strips of appropriate steam indicator tape.
6. Labels the package using a special water proof pen:
   - Date of sterilization
   - Load #
   - Bill of lading person preparing package

## Post Pack Checks:

1. Selects appropriate size package.
2. Places the steam indicator on package so it’s visible from outside the package.
3. All instruments must be in the open position or disassembled to their smallest parts.
4. Probes selected with plastic or tip protector.
5. Steams open end of package ensuring seal without wrinkles and accessible air. All air acts as a barrier to heat and steam.
6. Labels the package using a special water proof pen:
   - Date of sterilization
   - Load #
   - Bill of lading person preparing package.

## Autoclave:

1. Ensures weekly biological monitor results are on file and logged.
2. Describes proper procedure for Biological Monitoring referring to package directions.
3. Describes the proper procedure for a positive result.
4. Completes autoclave log each time autoclave is run, monitor is sent or maintenance is performed.
5. Follows manufacturer’s directions for the loading and operation of the autoclave ensuring that packages are loaded in a manner that allows for free steam and air circulation.
6. Places autoclave去世 in the same direction.
7. Sets autoclave controls for the appropriate type of packaging.
8. Does not ever use the “Unsteamed or Flash” cycles.
9. Autoclaves reason for instrument recall/sterilization and makes appropriate notation on log:
   - Failed biological monitor
   - Visible contamination: repackages and retestnerizes single package if only one.
   - Single package if only one.
   - Steam indicators have not changed to appropriate color (blue)
   - Should be washed & disinfected between each preparation.
10. Verifies knowledge and performance of routine maintenance per manufacturer’s recommendations.

## Notes:

- Has appropriate autoclave cleaner and maintenance supplies available (List):
  - Distilled water
  - Autoclave cleaner
  - Brushes

**Comments:**

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For BPHC-specific accreditation info:
- Brittnay Hull, Sr. Account Executive 630-792-5216
  (bhull@jointcommission.org)
- Pam Komperda, CHCA Project Manager 630-792-5551
  (pkomperda@jointcommission.org)
- Jeff Conway, Director, Government Programs 630-792-5717
  (jconway@jointcommission.org)
- Joyce Webb, PCMH Initiative Project Lead 630-792-5277
  (jwebb@jointcommission.org)
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