High-Level Disinfection (HLD) and Sterilization BoosterPak

The Joint Commission®

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Goal of this BoosterPak

To ensure work practices are carried out following regulatory standards and evidence-based guidelines for HLD and sterilization in order to minimize the potential risk of infection transmission to patients.

TARGETED AUDIENCE

Front-line staff conducting HLD and sterilization processes

Supervisor/Manager of front-line staff

Infection Preventionists

APPLICABLE SETTINGS

- Hospitals (HAP)/ Critical Access Hospitals (CAHs)
- Ambulatory (AMB)
- Office-based Surgery Practice Settings (OBS)

Become acquainted with these Standards

See the Appendix for Standards Explanation

Primary Standard Governing HLD and/or Sterilization Processes for All Settings:

Standard IC.02.02.01: Reducing the risk of infections associated with medical equipment, devices, and supplies

EP2: Performing intermediate, high-level disinfection and sterilization of medical equipment, devices, and supplies

Other Standards Governing HLD and/or Sterilization Processes for Each Setting:

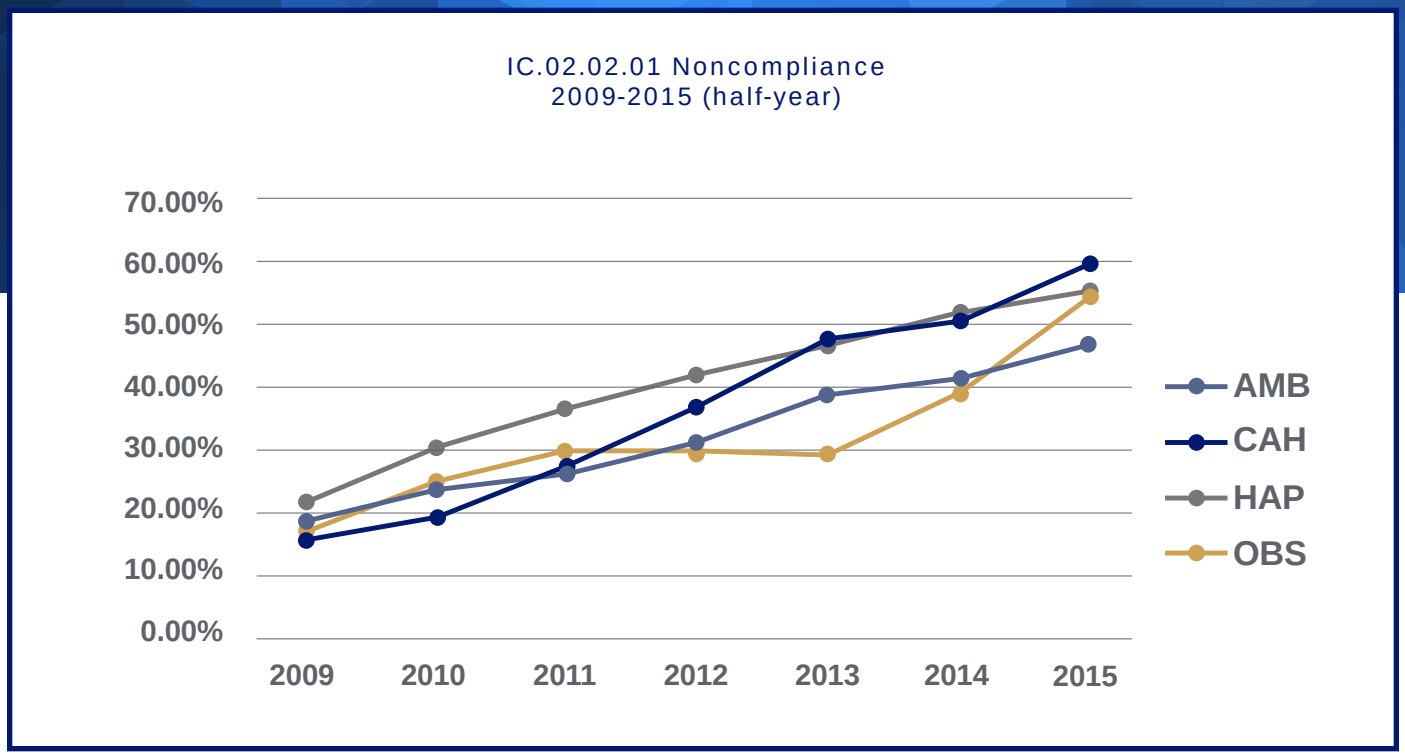
Standard	HAP	CAH	AMB	OBS
IC.01.01.01	●	●	●	●
IC.01.03.01	●	●	●	●
IC.01.05.01	●	●	●	●
IC.02.01.01	●	●	●	●
IC.02.02.01	●	●	●	●
IC.02.03.01	●	●	●	●
IC.03.01.01	●	●	●	●
HR.01.02.01	●	●	●	
HR.01.04.01	●	●	●	●
HR.01.05.03	●	●	●	●
HR.01.06.01	●	●	●	●
LD.01.03.01	●	●	●	●
LD.03.01.01	●	●	●	●
LD.03.03.01	●	●	●	●
LD.03.06.01	●	●	●	●
LD.04.01.05	●	●	●	●
LD.04.01.11	●	●	●	●
EC.02.05.01	●	●	●	●
EC.02.04.03	●	●	●	●
NPSG.07.01.01	●	●	●	●
NPSG.07.03.01	●	●		
NPSG.07.05.01	●	●	●	●

BACKGROUND

Healthcare organizations accredited by The Joint Commission continue to discover serious noncompliance issues with the Infection Prevention and Control Standard IC.02.02.01. These breaches are specific to HLD of semi-critical devices and sterilization of critical devices; both pose a potential risk of infection to patients.

During accreditation surveys, organizations that perform HLD and sterilization display wide variations in their processes. Penalties from identifying HLD and/or sterilization breaches that may pose an immediate threat to life (ITL) can include an adverse accreditation decision.

Noncompliance with Standard IC.02.02.01 by Setting



This graph illustrates the annual percentages from years 2009-2015 (half-year) of noncompliance with Standard IC.02.02.01 scored during accreditation surveys in the above noted settings, specific to surveyor identified findings with high-level disinfection and sterilization breaches. AMB= Ambulatory, CAH= Critical Access Hospitals, HAP= Hospitals, OBS= Office-based Surgery Practice Settings

THE SPAULDING CLASSIFICATION

The Spaulding Classification defines the minimum levels of disinfection (or sterilization) that should be employed according to the infection risk associated with a medical device. The system is divided into three categories of medical equipment and devices and their recommended levels of disinfection or sterilization, shown in the below chart.

Patient Contact	Examples	Device **Classification**	Minimum Disinfection Level
Intact Skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous Membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, vascular system		Critical	Sterilization

Source: *Healthcare Purchasing News* (June 2014)

A - Z

DEFINITIONS

Semi-critical Devices – come into contact with intact mucous membranes but do not ordinarily penetrate sterile tissue. *Examples:*

- Some endoscopes based on patient contact and manufacturer instructions for use
- Laryngoscope blades
- Respiratory therapy equipment

Critical Devices – enter normally sterile tissue or the vascular system. *Examples:*

- Surgical instruments
- Cardiac catheters
- Implants
- Some endoscopes based on patient contact and manufacturer instructions for use

High-level Disinfection (HLD) – the process of complete elimination of all microorganisms in or on a device, except for small numbers of bacterial spores. *Examples:*

- Glutaraldehyde
- Hydrogen Peroxide
- Ortho-phthaldehyde (OPA)

DEFINITIONS

Sterilization – validated process used to render a product free of all forms of viable microorganisms. *Examples:*

- Steam (preferred method for sterilization of critical instruments that are not damaged by heat, steam, pressure or moisture):
  - gravity-displacement steam
  - pre-vacuum steam
- Ethylene oxide (EO)
- Hydrogen peroxide gas plasma
- Peracetic acid-chemical sterilization

Immediate Threat to Life (ITL) – A threat that represents the most immediate risk, and has or potentially may have, serious adverse effects on the health or safety of the patient. These threats are identified on site by the surveyor.

REVIEW QUESTIONS

Q&A

Q. **Why is an understanding of the Spaulding Classification important?**

A. The Spaulding Classification defines the minimum levels of disinfection or sterilization required for the three different categories of medical devices based on intended use. Always defer to manufacturer's instructions for use for cleaning, disinfection, and sterilization recommendations.

Q. **What is High Level Disinfection (HLD)?**

A. High Level Disinfection is the process of complete elimination of all microorganisms in or on a device, with the exception of small numbers of bacterial spores.

Q. **How does one determine whether to HLD or sterilize a device or piece of equipment?**

A. Manufacturer instructions for use instructs the user on recommendations for HLD and/or sterilization.

Important Takeaways

- Incidences of non-compliance with Standard IC.02.02.01 are on the rise in Joint Commission accredited facilities.
- Reduce/eliminate infections due to improperly disinfected or sterilized medical devices by strictly implementing and following Standard IC.02.02.01, EP2, related Standards, and elements of performance (EPs).
- To properly disinfect or sterilize devices and instruments, **you must know in which Spaulding Classification Category** they belong and follow manufacturer instructions for use.

Leadership

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Standards Governing Leadership and Associated Elements of Performance (EPs)

STANDARD LD.01.03.01 – EP5
(DOES NOT APPLY TO OBS)

The governing body is ultimately accountable for the safety and quality of care, treatment, and services.

EP5: The governing body provides for the resources needed to maintain safe, quality care, treatment, and services.

EXAMPLES OF RESOURCES INCLUDE:

- Human Resources → Human resources are provided such as staffing orientation, training, and certification if required to support central sterile processing and/or high-level disinfection processes.
- Equipment → Equipment resources such as endoscopes, sterilizers, and surgical instruments are purchased and maintained, repaired, and replaced per manufacturer.
- Location → Appropriate space and location to safely conduct decontamination, high-level disinfection, sterilization, and storage is provided and maintained.

STANDARD LD.03.01.01
Create and maintain a culture of safety and quality.

EP3: Leaders provide opportunities for all individuals to participate in safety and quality initiatives.

EP4: Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.

EP5: Leaders create and implement a process for managing behaviors that undermine a culture of safety.

EP8: All individuals, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality.

EXAMPLES INCLUDE:

- Front-line Staff → Front-line staff feel safe and are supported to report breaches in high-level disinfection or sterilization.
- Speaking Up → Speaking Up to stop an error with high-level disinfection or sterilization is encouraged and supported.

STANDARD LD.03.03.01 – EP4

Leaders use hospital wide planning to establish structures and processes that focus on safety and quality.

EP4: Leaders provide the resources needed to support the safety and quality of care, treatment, and services.

EXAMPLES INCLUDE:

Achieving Goals

Achieving short and long-term goals with expected or anticipated growth of procedures that involve high-level disinfection and/or sterilization – to include off-site locations.

Designing

Designing high-level disinfection and sterilization work processes that focus on safety and quality to prevent breaches that could pose infectious risks to patients.

STANDARD LD.03.06.01 – EP4

Those who work in the hospital are focused on improving safety and quality.

EP4: Those who work in the hospital are competent to complete their assigned responsibilities.

EXAMPLES INCLUDE:

Training

High-level disinfection and sterilization are both complex multi-step processes that rely on competent individuals to assure that safety and quality are continually recognized as driving factors. Initial and on-going competency, training, and adhering to manufacturer's instructions for use and evidence-based guidelines are important to patient safety.

STANDARD LD.04.01.05

The organization effectively manages its programs, services, sites, and departments.

EP1: Leaders of the program, service, site, or department oversee operations.

EP3: The organization defines in writing the responsibility of those with administrative and clinical direction of its programs, services, sites, or departments.

EP4: Staff are held accountable for their responsibilities.

STANDARD LD.04.01.11

The organization makes space and equipment available as needed for the provision of care, treatment, and services.

EP2: The arrangement and allocation of space supports safe, efficient, and effective care, treatment and services.

EP4: The grounds, equipment, and special activity areas are safe, maintained, and supervised. (No CAH)

EP5: The leaders provide for equipment,supplies, and other resources. (No OBS).

LEADERSHIP INCLUDES:

CEO, Directors, management/supervisors, Infection Preventionists (those with oversight responsibilities).

LEADERSHIP

OR's | Clinics | ICU's, Units, Floors | Endoscopy
Central Sterile Processing | Dental | Sleep Apnea Study Centers

Leaders at the program, service, site, or department level are responsible for the care, treatment, and services provided.

- Leaders develop policies and procedures that utilize medical equipment, devices, and supplies that require high-level disinfection (HLD) and sterilization prior to use on patients.
- There should be clearly defined, written, managerial and/or supervisory oversight that includes knowledge and training of (HLD) and/or sterilization at the leadership level (this will provide safe and effective HLD and sterilization processes).
- Managerial staff have knowledge of and use evidence-based guidelines to develop education, training, and competency for high-level disinfection and sterilization.
- Front-line staff that are responsible for performing HLD and/or sterilization are initially and routinely monitored to assure that all steps are being conducted thoroughly and accurately (according to both the manufacturer's instructions for use and evidence-based guidelines).
- Specific job responsibilities are noted within the job qualifications of each individual/role. These includes HLD and/or sterilization tasks or oversight:
  - Upon hire;
  - On an ongoing frequency, as determined by the department hospital policy, or in accordance with law and regulation;
  - When new devices, supplies, or equipment are purchased; and
  - When there is a change in a staff member's role.

EXAMPLES INCLUDE:

OR Manager → An OR manager is now responsible for Central Sterile Supply (central sterile processing receives both instruments and endoscopes for HLD and sterilization).

Outpatient Clinic Manager → An outpatient clinic manager is now responsible for dental clinics (a decentralized location that conducts sterilization).

Technician → A central sterilization technician trained to perform sterilization processes is now expected to perform cleaning and processing of endoscopes.

REVIEW QUESTIONS

Q&A

Q. **According to Standard: LD.04.01.05 and EP1, who in the organization manages the programs, services, sites, and departments?**

A. The Leaders of the programs, services, sites, or departments oversee and manage operations.

Q. **How do front-line staff who perform HLD and sterilization processes know they are performing their jobs correctly?**

A. Front-line staff that are responsible for performing HLD and/or sterilization are initially and regularly monitored to assure that all steps are being conducted thoroughly and accurately.

Q. **Where can you find an individual's specific job responsibilities?**

A. It can be found in the individual's job qualifications.

Important Takeaways

- **The organization defines in writing the responsibility of** those with administrative and clinical direction of its programs, services, sites, or departments.
- Leadership is ultimately responsible for the care, treatment, and services provided within the organization.
- To be sure that front-line staff are performing HLD and sterilization processes thoroughly and accurately, they are to be monitored initially and regularly.

RESOURCES/LINKS

The following links are provided courtesy of the International Association of Healthcare Central Service Material Management (IAHCSMM):

Immediately available: No Cost Resources. To access IAHCSMM educational materials: **www.iahcsmm.org/education/online-lessons.html**

(Please note: access to the articles is free; readers will need to pay a fee to take the associated CE exam.)

134 **Lean Management Practices in Central Service Departments**
(Available until February 2017)

140 **Leadership Skills for New Central Service Supervisors**
(Available until February 2018)

Risk Assessment

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Primary Standard IC.01.03.01

The organization identifies risks for acquiring and transmitting infections.

INCLUDE THE FOLLOWING COMPONENTS AS PART OF YOUR RISK ASSESSMENT:

Identify all locations where all or part of High-level Disinfection (HLD) and Sterilization processes are conducted in your organization (centralized and de-centralized locations):

- Clinics
- Emergency Rooms
- OB-GYN Clinics
- ORs
- Central Sterile Processing
- Special Procedure Rooms
- Sleep Apnea Study Labs
- Endoscopy Rooms

Know where all scopes, probes, and devices requiring HLD and Sterilization are located in your organization:

- Clinics
- Emergency Rooms
- OB-GYN Clinics
- ORs
- Central Sterilization Processing
- Special Procedure Rooms
- Sleep Apnea Study Centers
- Intensive Care Units
- Radiology and Respiratory

Review, maintain, and conduct competency verification training of front-line staff and those that have oversight for HLD and Sterilization processes, including:

- Managers
- Supervisors
- Infection Preventionists

Know the location and accessibility of manufacturer's instructions-for-use for devices, equipment, supplies, and products such as:

- Sterilizers
- Endoscopes
- High-level disinfectant/Test Strips
- Ultrasonic Washers
- Instruments and automated endoscopic reprocessors (AERs)

Identify.
Know.
Review.
Insure.

Location and accessibility of current evidence-based guidelines for the use of front-line staff (including links to resources and websites; some may need to be purchased):

- AAMI:
  - ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities (preview at **http://my.aami.org/store/detail.aspx?id=ST58)**
  - ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities (preview at **http://my.aami.org/store/detail.aspx?id=ST79)**
  - ANSI/AAMI ST91, Flexible and semi-rigid endoscope processing in health care facilities (preview at **http://my.aami.org/store/detail.aspx?id=ST91)**

Insure that organizational/departmental policies and procedures are **current, reflect evidence-based guidelines, and the staff have knowledge** and access to these documents:

- Assure that staff conduct and articulate procedures that reflect content stated in the organizational/departmental Polices & Procedures Manual

Include key stakeholders involved in HLD and Sterilization processes in your risk assessment:

- Infection Preventionists
- Environmental Services
- Facilities/ENG
- Managers/Supervisors
- Front-line Staff
- Directors

Example of a Risk Assessment Chart

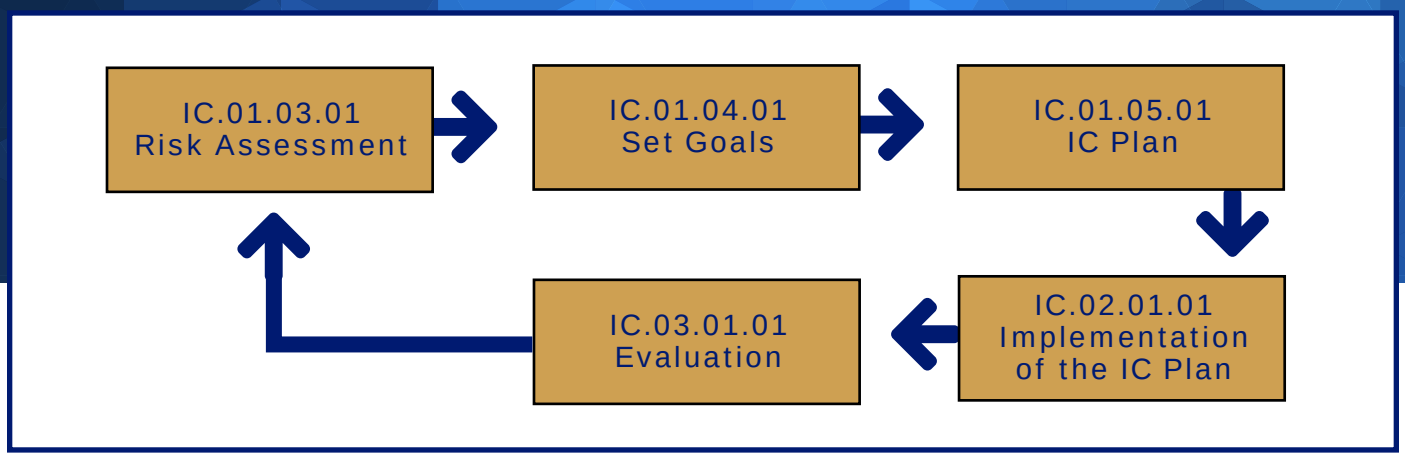
Infection Control Program Risk Assessment

Program Components	Probability					Risk/ Impact (Health, Financial, Legal, Regulatory)					Current Systems					Score
	Expect it	Likely	Maybe	Rare	Never	Loss of life/limb/ function	Temp loss of Function	Prolonged Length of Stay	Moderate Clinical/ Financial	Minimal Clinical/ Financial	None	Poor	Fair	Good	Solid	
	4	3	2	1	0	5	4	3	2	1	5	4	3	2	1	
High-level disinfection (HLD)																
Endoscopy																
GYN Clinic																
Sterilization																
OR																
Dental																
Labor & Delivery																

A risk assessment is conducted before HLD and sterilization goals are determined. Both HLD and sterilization if performed in your healthcare facility, should be included in your Risk Assessment and Infection Prevention and Control Plan, based on risk.

The IC Risk assessment is an ongoing, continual process, as risks continually change – as new products or pieces of equipment are purchased, new staff are hired, or a new program or service is added.

HLD and Sterilization Start with a Risk Assessment Process



KEY TO THE GRAPHIC:

- **IC.01.03.01 Risk Assessment** – The organization identifies risks for acquiring and transmitting infections.
- **IC.01.04.01 Goal –** Based on the identified risks, the organization sets goals to minimize the possibility of transmitting infections.
- **IC.01.05.01 Infection Control Plan –** The organization has an infection prevention and control plan.
- **IC.02.01.01 Implementation –** The organization implements its infection prevention and control plan.
- **IC.03.01.01 Evaluation –** The organization evaluates the effectiveness of its infection prevention and control plan.

DESCRIPTION OF THE GRAPHIC

IC.01.03.01 – Potential risks are related to HLD and sterilization – specify area or site
IC.01.04.01 – Goals are specific to identified risks related to minimizing the risk of transmission of infection with endoscopes, ultrasounds probes, and implants as examples.

- Include a time frame (monthly, quarterly, annually) for your goals
- Be specific (location or site, HLD or sterilization)
- Measurable (100%, or based on last year's result of 90%, increase incrementally)
- Be realistic in goal setting based on former data and feasibility

IC.01.05.01 Have an IC Plan and IC.02.01.01 Implementation of IC Plan

- Use of evidence-based guidelines
- Manufacturer's instructions for use
- Competency and training
- Managerial or supervisory oversight
- IC involvement

IC.03.01.01 Evaluation of IC Plan

- Implementation complete
- Goals met
- Decrease in HLD and/or sterilization breaches

RISK ASSESSMENT SHOULD INCLUDE THE FOLLOWING:

- What are your organization's vulnerabilities with HLD and/or sterilization?
- What is your volume of reprocessing for HLD and/or sterilization?
  – How many endoscope procedures do you conduct daily? Weekly?
- Where are procedures being conducted in your facility? Include off-site, decentralized locations in the risk assessment.
- Staff turnover. Competency and training issues. Frequency. Adequacy – Does it reflect details of the HLD and sterilization process? Documentation is kept up-to-date in employee file.
- Oversight of HLD and sterilization. Is the supervisor or manager who oversees the process of HLD and/or sterilization competent to monitor front-line staff performing these processes?
- Quality monitoring. Following manufacturer instructions for use and evidence-based guidelines for conducting HLD and sterilization.
  – Sterilization – physical, chemical, and biological indicators.
  – HLD – testing of HLD solution between each use, temperature of high-level disinfectant, time based on manufacturer instructions for use of the product, and test strips are used as indicated and not expired.
- Preventative maintenance of equipment and devices such as: sterilizers, automated endoscopic reprocessors (AERs), ultrasonic cleaners, and endoscopes.

REVIEW QUESTIONS

Q&A

Q. What components should be included in a Risk Assessment for HLD and Sterilization?

A. These are the seven components that were presented in this module:

- Identify all locations where all or part of HLD and Sterilization processes are conducted (centralized and de-centralized locations);
- Know where all scopes, probes, and devices requiring HLD and Sterilization are located in your organization;
- Review, maintain, and conduct ongoing competency and training of front-line staff, and those that have oversight for HLD and Sterilization processes;
- Know the location and accessibility of the manufacturer's instructions-for-use for devices, equipment, supplies, and products which are involved in the HLD or sterilization process;
- Become familiar with the location and accessibility of current evidence-based guidelines for front-line staff use;
- Insure that organizational/departmental policies and procedures are current, reflect evidence-based guidelines, and that the staff have knowledge and access to these documents; and
- Include key stakeholders involved in HLD and Sterilization processes in your risk assessment process review.

Q. When are Risk Assessment goals concerning HLD and Sterilization determined?

A. The goals are determined/set after a Risk Assessment has been conducted.

Q. What would a specific goal look like based on an HLD or Sterilization Risk Assessment?

A. An example of a specific goal would be: By a specific date, 100% of surgical instruments transported to central sterile processing will be pre-cleaned at the point-of-use to prevent blood/body fluids/bioburden from hardening on the instruments as per evidence-based guidelines.

Important Takeaways

- The Infection Control Risk assessment is an ongoing and continual process.
- The IC Risk Assessment must include:
  - **Assessment (identification) of risks for acquiring and** transmitting infections related to high-level disinfection and sterilization processes;
  - Goals based on the results of the Risk Assessment are to minimize the possibility of transmitting infections to patients;
  - Development and implementation of the infection prevention and control plan; and
  - Evaluation of the effectiveness of the organization's infection prevention and control plan annually and **whenever risks significantly change.**
- All stakeholders must be included in any Risk Assessment in order to create both an accurate and successful Infection Control Plan. Stakeholders include directors, managers supervisors and front line staff of multiple departments.

RESOURCES/LINKS

"Using the Risk Assessment to Set Goals and Develop the Infection Prevention and Control Plan." Joint Commission Resources. Web. **http://www.jcrinc.com/using-the-risk-assessment-to-set-goals-and-develop-the-infection-prevention-and-control-plan/**

Sterilization

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Sterilization and The Spaulding Classification

Use sterilization on critical devices that enter sterile tissue or the vascular system.

TARGETED AUDIENCE

Front-line staff conducting sterilization processes

Supervisor/Manager of front-line staff

Infection Preventionists

APPLICABLE SETTINGS

- Hospitals (HAP)/ Critical Access Hospitals (CAHs)
- Ambulatory (AMB)
- Office-based Surgery Practice Settings (OBS)

APPLICABLE MEDICAL DEVICES

Those devices included in the critical category of the Spaulding Classification (a device that enters sterile tissue or the vascular system). Such devices should be sterilized, which is defined as the destruction of all microbial life. *Examples:*

Surgical Instruments

Orthopedic Implants

Dental Instruments

Invasive Catheters

Primary Standard Governing HLD and Sterilization for All Settings:

Standard IC.02.02.01: Reducing the risk of infections associated with medical equipment, devices, and supplies

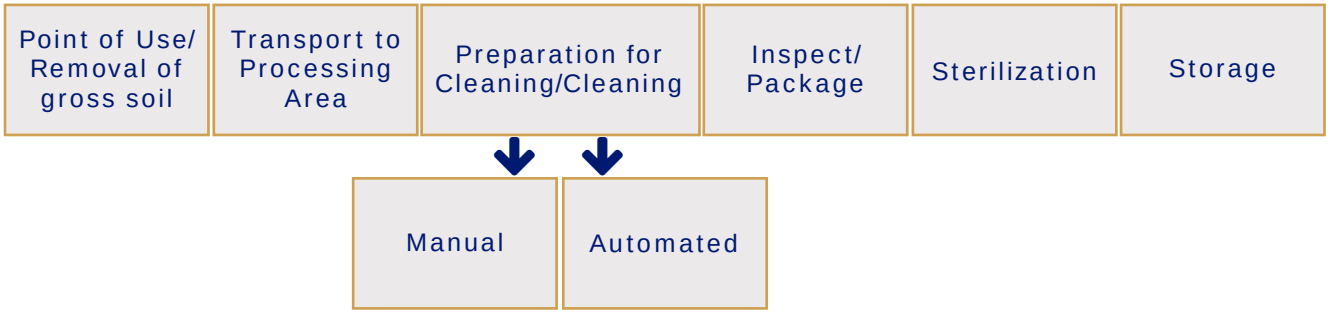
EP2: Performing intermediate, high-level disinfection and sterilization of medical equipment, devices, and supplies

Important Things to Know:

Important

- All locations where sterilization is conducted in your organization and where instruments, devices, and equipment used for procedures that require reprocessing by sterilization are kept (centralized and de-centralized locations, such as clinics, ERs, and L&Ds)
- Initial and on-going competency and training of front-line staff and those with oversight for sterilization processes
- Location and accessibility of manufacturers' instructions- for-use (sterilization related equipment, devices, and supplies)
- Location and accessibility of current sterilization evidence-based guidelines for front-line staff use (know which guidelines have been selected and where are they located)
- Make sure that sterilization policies and procedures are current, reflect sterilization evidence-based guidelines, and that staff have a working knowledge and access to these documents
- Include key stakeholders in sterilization process (Infection Preventionist, Environmental Services, Facilities/ENG, leadership, central sterile manager or supervisor, OR manager and front-line staff)
- Contracted services for equipment/loaner instrumentation:
  – How are these services tracked and monitored?
  – Does equipment/loaner instruments arrive in sufficient time to reprocess?

Reprocessing Process for Sterilization



POINT-OF-USE

CHECKLIST FOR STERILIZATION PROCESS

Point-of-Use

- ❑ Procedure completed
- ❑ Pre-cleaning with a product recommended for pre-cleaning with manufacturer's instructions-for-use followed, that is applied at point-of-use in the procedure room or O.R. to remove blood, body-fluids, and bioburden from items that are to be re-processed based on manufacturer's instructions-for-use and evidence-based guidelines
- ❑ Items labeled as single-use disposable are disposed of and not reprocessed
- ❑ Use of a foam, gel, spray solution, or moist towel indicated per manufacturer to keep instruments and devices moist during transport prevents blood/body fluids/ bioburden from hardening on the equipment

Notes:

– Instruments, devices, and supplies are to be kept moistened to make it easier to clean in the decontamination room. This is particularly true if instruments have to wait to be cleaned because other areas are also transporting instruments to the decontamination area

– Pre-cleaning is the initial step to the sterilization process

TRANSPORT

Transport to Decontamination Area

- ❑ Items are contained to protect the transporter and others from contents within the container
- ❑ Items are to be kept moist during transport to prevent hardening of bioburden
- ❑ The type of container used is based on what is being transported
- ❑ All containers must be leak-proof, puncture-proof, and labeled as biohazardous
- ❑ Examples: bins with lids, impermeable bags, etc.

DECONTAMINATION

Decontamination – General

- Observe and monitor for carts of contaminated instruments left unattended in corridors and for instruments left soaking in containers in de-centralized locations for extended periods of time
- Delaying the decontamination process can cause bioburden to dry on instruments, making them more challenging to clean

In the Decontamination Room

- Personal Protective Equipment (PPE) is worn and includes:
  - Hair covering/cap
  - Face mask/shield
  - Fluid resistant gown
  - Gloves used should be durable to prevent tearing and leaking of chemicals and/or contaminated fluids when the user's hands are under water
- Note a distinct flow and separation of dirty and clean processes that minimizes the risk of cross-contamination

Decontamination

- Hinged items are opened to assure access to proper cleaning
- Cleaning:
  - Manual or performed by hand
  - Mechanical or automated process
  - Combination of manual and automated based on manufacturer's instructions for use and evidence-based guidelines

PREPPING

Prepping and Packaging

- Examples of packaging materials:
  - Woven, non-woven textile wrappers
  - Rigid sterilization containers
  - Paper/plastic pouches (peel packs)
- Items are wrapped and placed in paper/plastic peel-pouches based on what it is and manufacturer's instructions-for-use (IFU)
- Double paper/plastic peel-pouches are utilized as indicated by the manufacturer instructions-for-use, with evidence-based guidelines being followed. No folding over of the inner paper/plastic peel pouch, as this may prevent the sterilant from contacting the contents of the package
  - Use the proper size pouch for the proper instruments

STERILIZATION

Sterilization

- Cleaning, maintenance, and record keeping/documentation of sterilizer(s) based on manufacturer's IFU
- Cycles of sterilizer – test all cycles that your sterilizer is capable of performing regardless of the cycle you use most often:
  - Gravity displacement
  - Dynamic air-removal

STERILIZATION

Sterilization – Steam

- Is the most commonly used process for sterilizing instruments, trays, and cassettes
- According to the CDC, steam under pressure is the process of choice whenever possible as it is considered safe, fast, and the most cost-effective for health care facilities
- Steam sterilizers come in many different sizes, and sterilizer cycles can vary among manufacturers. The cycle a sterilizer runs can typically be found in the sterilizer manual. The following are examples of standard cycle parameters (AAMI ST79, AORN) for packaged instruments. (The cycle selected should be appropriate for the device(s) being sterilized per the medical device manufacturer's IFU for sterilization.)
  - Gravity – 121°C/250°F for 30 minutes exposure and 15–30 minutes drying time
  - Gravity – 132°C/270°F for 15 minutes exposure and 15–30 minutes drying time
  - Gravity – 135°C/275°F for 10 minutes exposure and 30 minutes drying time
  - Dynamic Air Removal – 132°C/270°F for 4 minutes exposure and 20–30 minutes drying time
  - Dynamic Air Removal – 135°C/275°F for 3 minutes exposure and 16 minutes drying time

Sterilization – Other Commercially Available Sterilization Processes

- Chemical vapor
- Dry heat
- Ethylene oxide
- Vaporized hydrogen peroxide
- Ozone

Each of these processes offer advantages and disadvantages. The decision as to which sterilization process the health care facility should choose lies with the instrument manufacturer and what was validated in their instructions-for-use. For patient safety the process must be compatible so as not to cause damage, and must be efficacious to ensure sterility. For additional information refer to CDC Guidelines on HLD and Sterilization. Reference on page 11.

STORAGE

Sterile Storage

- Limited access, traffic controlled area
- Ventilation, temperature, and humidity (refer to evidence-based guidelines)
- Housekeeping – routine cleaning of this area
- Shelf life – event-related versus expiration/date related
  - Assures sterility maintenance
  - Inventory control
- Sterile storage area must be a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes
- Store sterile items so the packaging is not compromised (e.g., punctured, bent)
- Sterilized items include the following records: lot number, load contents, temperature and exposure time, reviewer initials, Bowie-Dick testing, chemical indicator and biological indicator results as appropriate

MONITORING

Table 6 – Sterilization Process Monitoring Recommendations

Routine load release		Routine sterilizer **efficacy monitoring**	**Sterilizer qualification** testing (after installation, relocation, malfunctions, major repairs, sterilization process failures)	Periodic product quality assurance testing
Nonimplants	Implants			
Physical monitoring of cycle External and internal chemical indicator monitoring of packages Optional monitoring of the load with a PCD containing one of the following: – a BI – a BI and a Class 5 integrating indicator – a Class 5 integrating indicator – a Class 6 emulating indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator	Physical monitoring of cycle External and internal chemical indicator monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In flash sterilization cycles, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	Physical monitoring of cycle External and internal chemical indicator monitoring of packages For sterilizers larger than 2 cubic feet and for flash sterilization cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack	Physical monitoring of cycle Placement of BIs and, CIs within product test samples

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Table 7 – Types and Applications for Use of Sterilization Monitoring Devices

Monitor	Frequency of Use	Application (release of sterilizer, package, load)
PHYSICAL MONITORS		
Time, temperature, and pressure recorders, displays, digital printouts, and gauges	Should be used for every load of every sterilizer.	Part of load release criteria.
CHEMICAL INDICATORS (CIS)		
External CIs Class I (process indicators) **Bowie-Dick-type indicators** Class 2 (Bowie-Dick)	Should be used on outside of every package unless the internal CI is visible. For routine sterilizer testing (dynamic-air-removal sterilizers only), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air-removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.	Part of load and package release criteria. Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.
Internal CIs	Should be used inside each package. Should be used in periodic product quality assurance testing.	Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.
Class 3 (single-variable indicator) Class 4 (multi-variable indicator)	May be used to meet internal CI recommendation.	Part of package release criteria at use site; NOT to be used for release of loads.
Class 5 (integrating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor nonimplant sterilizer loads. Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.
Class 6 (emulating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor sterilizer loads.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations.
Biological indicators (BIs)	Within a PCD, may be used to monitor nonimplant loads. Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 integrating indicator. Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for wrapped items; for table-top sterilization, should be run in a fully loaded chamber; for flash sterilization, should be run in an empty chamber. Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. Should be used for periodic product quality assurance testing.	Part of load release criteria. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known. Part of sterilizer/load release and recall criteria. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

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MONITORING

Quality Monitoring – Mechanical or Physical Indicator

- A visible monitor such as a printout, used to determine if critical sterilization parameters for each cycle (time, temperature, and pressure) were met during the process.
- The printout should be reviewed and signed at the end of each cycle verifying that all sterilization parameters were met.

Quality Monitoring – Chemical Indicator

- A chemical indicator is a monitoring device that is used to monitor one or more critical parameters required for sterilization. This is typically noted by a color change on a tape or strip that indicates the item has been exposed (or processed versus not processed) to the sterilization process.
- This does NOT indicate that the item is sterile.
- A chemical indicator should be used inside each package to be sterilized and also on the exterior of the package if the internal indicator is not visible from the outside.
- There are 6 classes of CIs. The Class 5 indicators are integrating indicators which react to all three of the critical variables and are appropriate for all steam cycles. A Class 5 indicator is used with a biological indicator (BI) for all implant loads.
- Dynamic air-removal test (Bowie-Dick test) is a diagnostic test performed daily to determine adequacy of air removal from the chamber of a pre-vacuum steam sterilizer. This test is not a test of sterilization.

Quality Monitoring – Biological Indicator

- These are monitoring devices commercially prepared with highly resistant spores that tests the effectiveness of the sterilization method in use.
- This indicator demonstrates that conditions necessary to achieve sterilization were met during the cycle being monitored.
- Steam sterilizers should be tested with a BI at least weekly and preferably daily.
- Consult manufacturer's instructions for testing of other sterilizers such as for ethylene oxide.
- All loads containing an implant should be monitored with a BI and the implant should be quarantined until results of the BI are known.

Quality Monitoring – AAMI ST79:2010 and Amendments

- 10.7.2.3 Test procedure: Each day that Biological Indicator (BI) tests are run, at least one BI that is from the same lot but has not been exposed to the sterilant should be incubated as a control in each incubator to verify the pre-sterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature. Upon completion of the incubation period, the test and control results should be read and recorded.
- 10.6.2 Release criteria for non-implants: Load release should be an active decision that is based on the evaluation of all available data from the sterilization process for the particular load. The decision to release a load should be made by an experienced and knowledgeable person at the conclusion of the sterilization cycle. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed and used on a patient.

MONITORING

Quality Monitoring – Per AAMI ST79:2010 *(continued)*

- 10.6.3 Release criteria for implants:
  - As with all cycles, an experienced and knowledgeable person should review the sterilizer chart or printout at the end of the sterilization cycle, as well as the results of other indicators that have been used to monitor the sterilization process. The load should be quarantined until the results of the BI testing are available (CDC, 2008).
  - Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.
- When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it may be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. (See Annex L for examples of an implant log and an exception form.) It is critical that this documentation be fully traceable to the patient.
- Emergency situations should be defined in written guidance, developed in consultation with infection prevention and control, the surgeon, the OR manager, and risk management. Steps should be taken to reduce the frequency of emergency releases of implantable items. For example, ongoing periodic reviews of the exception forms and implant logs could reveal consistent patterns of events that are causing emergency release and that could be improved upon or reduced.

Annex L (Informative) – Example of Documentation of Premature Release of Implants

Implantable Devices Load Record

Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/ time and BI result	Early release?	Date/time released to OR	Released by (full name)

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Quality Monitoring – Event-related or Timed Expiration

- The shelf life of a packaged sterile item may be event related as stated by the organization in their policy and procedure, based on evidence-based guidelines and manufacturer's instructions for use.
- If the integrity of the packaging is compromised, such as being wet or torn, then the item must be repackaged and reprocessed before use; otherwise the item may be used if no event has occurred to compromise the integrity of the packaging.
- Some organizations may use time storage which means that the label on the sterile package is applied at sterilization with an expiration date; when the expiration date occurs, the package must be reprocessed.

Quality Monitoring – Immediate Use Steam Sterilization (IUSS)

- **Defined:** Immediate use is the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediate Use Steam Sterilization (IUSS) is for items not intended to be stored and used later.
- **Consider the following before IUSS:** Can the item undergo IUSS? Review and adhere to manufacturer's instructions for use regarding cycle type, temperature setting, exposure time, and drying times.

MONITORING

- IUSS does not imply that reprocessing steps are acceptably omitted, such as appropriate cleaning and transport.
- Items are placed in approved/validated containers/trays for IUSS.
- Why is IUSS being conducted? – out of convenience, limited instruments/equipment for the number of cases/procedures being conducted: these are reasons that are **NOT** supported by evidence based guidelines and should be addressed to eliminate this practice.
- Loaner practices – receipt of loaner instruments too close to the scheduled case/procedure time (review contract and address directly with vendor).

Reference: **http://www.apic.org/Resource_/TinyMceFileManager/Position_Statements/Immediate_Use_Steam_Sterilization_022011.pdf**

REVIEW QUESTIONS

Q&A

Q. **What is the definition of critical devices, according to the Spaulding Classification?**

A. Those devices that are included in the critical category of the Spaulding Classification are devices that enter sterile tissue or the vascular system. Such devices should be sterilized, which is defined as the destruction of all microbial life.

Q. **When a procedure is over, why should you pre-clean the instruments as soon as possible and not delay the transport to the decontamination area?**

A. Omitting or delaying pre-cleaning may cause bioburden to dry on instruments, making them more challenging to clean and sterilize.

Q. **What are the three types of indicators used to monitor sterilization parameters?**

A. Mechanical or physical indicators, chemical indicators, and biological indicators. All three parameters serve a purpose in quality monitoring of the sterilization process.

Important Takeaways

- **Become familiar with the Spaulding Classification and** understand which instruments fall within the critical category. Once you know this, you will be able to determine which instruments/devices must undergo sterilization as opposed to HLD.
- Regardless of your position, learn all of the steps in the sterilization process from Point-of-Use to the end of the process, when the instruments are stored in the Sterile Storage Room.
- Understand what Immediate Use Steam Sterilization (IUSS) is and the criteria used to determine if devices can undergo this method of sterilization.

RESOURCES/LINKS

"2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities." Centers for Disease Control and Prevention (2008)

2015 AORN Guidelines for Perioperative Practice

Association for Professionals in Infection Control. *APIC Text of Infection Control and Epidemiology. 4th Edition.* 2014. Print

"Checklist for Cleaning, Disinfection and Sterilization of Instruments and Flexible Scopes:" *Agency for Healthcare Research and Quality.* **http://ascsafetyprogram.org/about-the-program/press-release?download=136:c2-checklist**

"Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." *ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 (Consolidated Text)*

"Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care:" *Centers for Disease Control and Prevention*. **http://www.cdc.gov/HAI/settings/outpatient/checklist/outpatient-care-checklist-observations.html**

The following links are provided courtesy of the International Association of Healthcare Central Service Material Management (IAHCSMM):

Immediately available: No Cost Resources. To access IAHCSMM educational materials: **www.iahcsmm.org/education/online-lessons.html**
(Please note: access to the articles is free; readers will need to pay a fee to take the associated CE exam.)

133 **Understanding Biofilm**
(Available until December 2016)

137 **Cleaning Complex Instruments**
(Available until September 2017)

138 **Low-Temperature Sterilization**
(Available until October 2017)

243 **Laparoscopic and Robotic Surgical Instruments**
(Available until June 2017)

244 **Decontamination**
(Available until August 2017)

245 **Instrument Inspection**
(Available until October 2017)

251 **Ophthalmic Instrumentation**
(Available until October 2018)

603 **Documentation for Instrument and Equipment Reprocessing**
(Available until February 2017)

Environment of Care

The Joint Commission®

Standards Governing the Environment of Care Standards

Applicable Standards that apply and are related to sterilization and/or high-level disinfection (HLD) processes include the following::

STANDARD EC.02.04.03

The organization inspects, tests, and maintains medical equipment.

EP4: The organization conducts performance testing of and maintains all sterilizers These activities are documented.

APPLICABLE SETTINGS

- Hospitals (HAP)/ Critical Access Hospitals (CAHs)
- Ambulatory (AMB)
- Office-based Surgery Practice Settings (OBS)

EXPLANATION OF STANDARD

Identify, monitor, and document (maintain a log) all sterilizers for cleaning, maintenance, and repairs. This includes all de-centralized or off-site locations with table-top sterilizers. Adhere to manufacturer's instructions-for-use.

This may include working with other departments such a Facilities/ENG/Plant Operations and/or contracted staff to assure compliance.

If an alternative equipment maintenance strategy is used, see standard EC.02.04.01 EP 4 through 7 for assessment and implementation instructions.

STANDARD EC.02.05.01

The organization manages risks with its utility systems.

APPLICABLE SETTINGS

- EP15 (Manuals): Hospitals and Critical Care Hospitals
- EP6 (Manuals): Ambulatory and Office-based Surgery Practice Settings

EXPLANATION OF EP15 AND EP6

In areas designed to control airborne contaminants (such as biological agents, gases, fumes, and dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies.

Note: Areas designed for control of airborne contaminants include spaces such as:

- Operating rooms
- Special procedure rooms (where a sterile procedure field is required)
- Caesarean Delivery rooms
- Rooms for patients diagnosed with or suspected of having airborne communicable diseases (for example, pulmonary or laryngeal tuberculosis)
- Patients in "protective environment" rooms (for example, those receiving bone marrow transplants)
- Laboratories
- Pharmacies
- Sterile supply rooms

The purpose of providing and maintaining controlled conditions in the OR, special procedure rooms, Caesarean delivery rooms, airborne infection isolation rooms, laboratories, pharmacies, and sterile storage rooms is to reduce the risk of airborne contamination.

Room temperature, humidity, and ventilation should adhere to local, state, and federal policies and regulations.

For further information, see Guidelines for Design and Construction of Health Care Facilities, 2010 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE)

PER EC.02.05.01 EP 15 (HAP AND CAH); PER EC.02.05.01 EP 6 (AHC AND OBS)

- The organization is expected to comply with the specified filtration, room pressurization, and air exchange rates listed in the ventilation table as determined by the rules and regulations adopted by the organization's controlling authority for health care construction and operations (typically their state health department or licensing entity).
- If the organization's authority is silent, then TJC recognizes Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2010 edition, where the ASHRAE I70, Ventilation Table 7-1 has been adopted.
- Other guidelines such as those published by AORN or AAMI, can be utilized by the organization; again, this is only if the controlling authority is silent on the issue. Organizations are to make the TJC surveyors aware of these requirements at the time of their survey.
- There are clinics in which high level disinfection and table top sterilization may be performed. Many of these areas do not have separate rooms for decontamination and disinfection. They have, however, been set up to work in a one directional manner to accommodate the dirty to clean layout of the room. This practice and process may be acceptable as long as it reflects a dirty to clean process based on evidence-based guidelines, and supporting departmental policy and procedure, with no risk of cross contamination.
- Additionally, if the controlling authority (i.e., state health department or licensing entity) is silent at the time for design – especially for the air exchanges, filtration, and pressure relationships that would be required – then the organization must be able to provide documentation that this space meets state regulations or 2010 FGI guidelines.
- There are no ventilation requirements for spaces where sterilization and/or decontamination occurs in office-based surgery practices or general outpatient facilities that are not ambulatory surgery centers (ASCs).
- For high-level disinfection of semi-critical devices, refer to ventilation recommendations noted in ASHRAE 170-2008. Table 7-1. All other ventilation expectations would follow those based on the chemical used (i.e., the Safety Data Sheet requirements).

GUIDELINES FOR STERILIZATION

Design requirements are not the same as clinical practice recommendations. Each has a distinct purpose and intent. The ASHRAE/ASHE standards and FGI guidelines are intended to establish the minimum design requirements and criteria that must be met to construct an HVAC system that will support clinical functions during the life of a building. The AAMI and AORN guidelines are intended to guide the daily operation of the HVAC system and clinical practice once the health care facility is occupied.

Joint Interim Guidance: HVAC in the Operating Room and Sterile Processing Department

FGI 2010 Guidelines

Design Parameters

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	RH (k), %	Design Temperature (l), ºF/ºC

REVIEW QUESTIONS

Q & A

Q. **How would you explain Standard EC.02.04.03 to a new employee?**

A. The organization identifies, monitors, and documents (maintain a log) all sterilizers for cleaning, maintenance, and repairs. This includes all de-centralized or off-site locations with table-top sterilizers. Adhere to manufacturer's instructions-for-use.

Q. **Standard EC.02.05.01 states: the organization manages risks with its utility systems. Why is it important to maintain controlled conditions via the ventilation system, especially in certain areas such as the O.R. and special procedure rooms?**

A. The purpose of providing and maintaining controlled conditions in the OR, special procedure rooms, Caesarean delivery rooms, airborne infection isolation rooms, laboratories, pharmacies, and sterile storage rooms is to reduce the risk of airborne contamination.

Q. **If a clinic does not have a separate room in which they perform high level disinfection or table top sterilization, what is one of the most important rules they must follow in order for this to be acceptable?**

A. This practice and process may be acceptable as long as it reflects a dirty to clean process based on evidence-based guidelines and supporting departmental policy and procedure, with no risk of cross contamination.

Important Takeaways

- According to Standard EC.02.04.03, EP4: health care facilities must identify, monitor, and document (maintain a log) all sterilizers for cleaning, maintenance, and repairs. This includes all de-centralized or off-site locations with table-top sterilizers. Adhere to manufacturer's instructions-for-use.
- Standard EC.02.05.01, EP15 and EP6 addresses the health care facility's ventilation system. It's important to understand how the ventilation system works to reduce airborne contaminants:
  - In areas designed to control airborne contaminants (such as biological agents, gases, fumes, and dust), the ventilation system must provide appropriate **pressure relationships, air-exchange rates, and filtration efficiencies.**
  - When functioning properly, the ventilation system plays an essential role in minimizing the spread of contaminants and infection.
- Health care organizations are expected to comply with **the specified filtration, room pressurization, air exchange** rates, temperature ranges and relative humidity ranges listed in the ventilation table as determined by the rules and regulations adopted by the organization's controlling authority for health care construction and operations (typically their state health department or licensing entity).

RESOURCES

AORN 2015 Guidelines for Perioperative Practice – Guideline for Sterilization

Guidelines for Design and Construction of Health Care Facilities, 2010 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE)

State licensing rules

High-level Disinfection

The Joint Commission®

High-level Disinfection (HLD)

Use HLD on semi-critical devices that come into contact with mucous membranes and/or non-intact skin.

TARGETED AUDIENCE

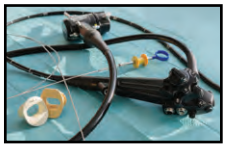
- Front-line staff conducting HLD processes
- Supervisor/Manager of front-line staff
- Infection Preventionists

APPLICABLE SETTINGS

- Hospitals (HAP)/ Critical Access Hospitals (CAHs)
- Ambulatory (AMB)
- Office-based Surgery Practice Settings (OBS)

APPLICABLE MEDICAL DEVICES

Devices that are included in the semi-critical category of the Spaulding Classification (Devices that come into contact with intact mucous membranes but do not ordinarily penetrate sterile tissue). *Examples:*



Endoscope*

Bronchoscope

Laryngoscope Blades

Anorectal Catheters

PRIMARY GUIDE FOR HLD IN ALL SETTINGS

Standard IC.02.02.01

Reducing the risk of infections associated with medical equipment, devices, and supplies

EP2: Performing intermediate, high-level disinfection and sterilization of medical equipment, devices, and supplies

Important Things to Know

Important

- All locations where HLD is conducted in your organization (centralized and de-centralized locations)
- Where all scopes, probes, and devices requiring HLD are located (clinics, ERs, ICUs, Sleep Study Centers, etc.)
- Initial and on-going competency and training of front-line staff, and those that have oversight for HLD processes
- Location and accessibility of manufacturer's instructions-for-use (HLD related equipment, devices, and supplies)
- Location and accessibility of current HLD evidence-based guidelines for front-line staff use
- Make sure that HLD policies and procedures are current, reflect HLD evidence-based guidelines, and that staff have knowledge and access to documents
- Include key stakeholders in HLD process (Infection Preventionist, Environmental Services, Facilities/ENG, leadership, front-line staff) and managers/supervisors

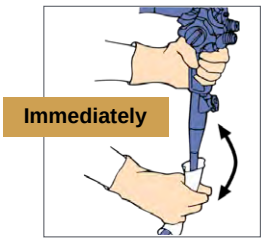
THE STEPS NECESSARY TO THOROUGHLY CLEAN AND HIGH-LEVEL DISINFECT IMMERSIBLE GI FLEXIBLE ENDOSCOPES

Remember: Follow OSHA Bloodborne Pathogen Regulations and Standard precautions when Handling Contaminated Endoscopes

All the steps of precleaning, leak testing, cleaning, and rinsing must occur to prepare the endoscope for either a manual or automated disinfection process.

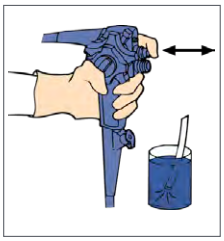
GI flexible endoscopes normally come in contact with intact mucous membranes and are classified by CDC guidelines as semicritical medical devices minimally requiring high level disinfection. Chemicals used to achieve HLD are capable of sterilization but when used at shorter contact times will destroy all vegetative bacteria, viruses, fungi, mycobacteria and some but not all spores. Only chemicals cleared by the FDA as high-level disinfectants or sterilants should be used for reprocessing endoscopes. Follow the manufacturer instructions for use for high-level disinfectants. This includes immersion or contact time, temperature of the high-level disinfectant, and required documented quality monitoring parameters.

1 PRECLEANING

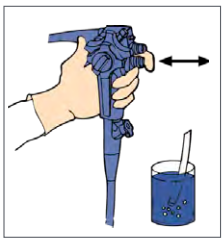


Wipe exterior of scope with endoscopic detergent.

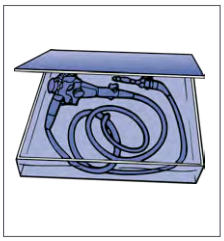
Note: Use a detergent formulated for use with endoscopes. Do not use household or dish detergent.



Suction scope with endoscope detergent until fluid is clear and end by suctioning air to clear fluid from scope. Flush auxiliary water channel even if it was not used.



Clear the air and water channels according to the manufacturer's instruction.

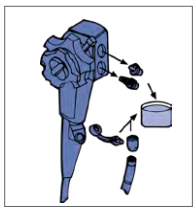


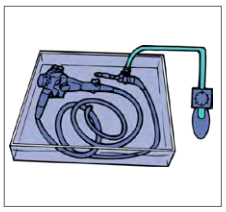
Place fluid-tight video cap on scope and bring scope to reprocessing area in covered container.

Note: Two channel endoscope require aspiration of detergent through both channels.

2 LEAK TESTING

Detach all removable parts except for fluid-tight video cap.



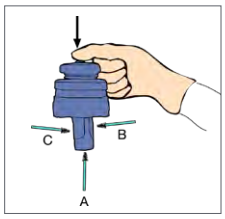


Leak test the endoscope according to the manufacturer's instructions.

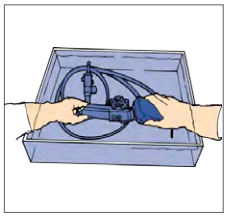
Note: If a leak is detected, follow the manufacturer's instructions for decontamination to avoid further damage.

3 MANUAL CLEANING

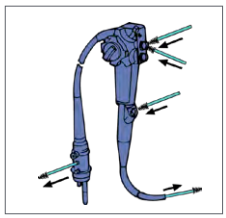
Scrub, brush, soak and rinse all removable parts in fresh endoscope detergent.



For the suction valve depress button to clean valve channel opening.

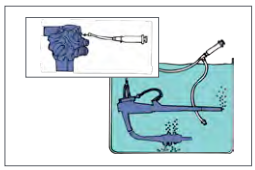


Immerse and thoroughly clean exterior of the endoscope in endoscope detergent using a lint free sponge or cloth.



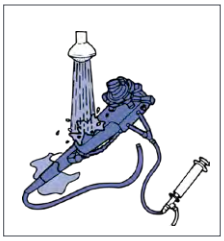
Brush all accessible channels.

Note: Clean brush each time it exits distal tip and umbilical cord. Brushing should be repeated until no debris is visible on the brush.

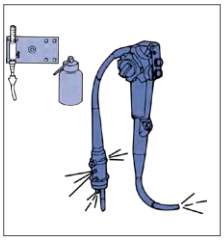


Attach cleaning adapters to endoscope. Immerse and soak the endoscope and its internal channels for the period specified by the label. Flush detergent solution through all of the following channels (suction, biopsy, air/water, accessory and elevator wire) until clear of debris.

4 RINSE AFTER CLEANING

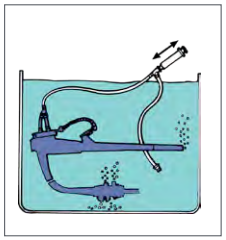


Rinse the Endoscope and removable parts thoroughly under running water to remove residual detergent. Flush all channels with water.



Purge all channels with air. Note: Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the HLD used in subsequent steps.

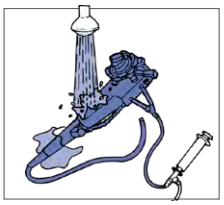
5 DISINFECTANT/STERILANT



Immerse the cleaned, rinsed and air-purged endoscope and all removable parts in a high-level disinfectant or sterilant. Using the cleaning adapters, fill all channels with the high-level disinfectant or sterilant until no air bubbles are seen.

Note: If an automated reprocessor is used, place the endoscope in the reprocessor and attach all channel adapters according to the manufacturer's instructions, Place valves and other removable parts into the soaking basin of the reprocessor unless the reprocessor has a dedicated space for the accessories, reprocess these items separately.

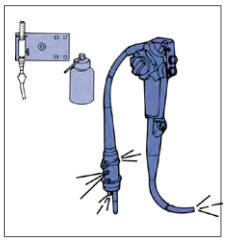
6 RINSE AFTER HIGH-LEVEL DISINFECTANT



Thoroughly rinse all surfaces and channels of the endoscope and its removable parts with water to remove all traces of the High-level disinfectant or sterilant.

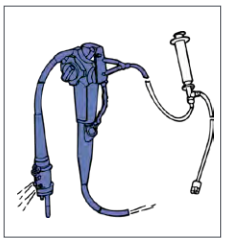
Note: If an automated reprocessor is used, ensure that rinsing is performed by the machine.

7 DRYING



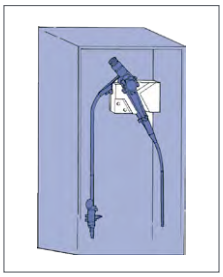
Purge all channels with air.

Note: Avoid excessively high air pressure.



Flush all channels with 70-80% alcohol to facilitate drying. Purge all channels with air.

8 STORAGE



Hang endoscopes vertically in a clean, well-ventilated and dust-free area.

Note: Caps, valves and other detachable components removed per manufacturer's instructions.

GENERAL

CHECKLIST FOR CLEANING, HIGH-LEVEL DISINFECTION, AND/OR STERILIZATION OF INSTRUMENTS AND FLEXIBLE SCOPES

- ❑ Copy of manufacturers' current instructions for cleaning, disinfection, and/or sterilization available for each instrument or scope
- ❑ Copy of manufacturers' current instructions for use of sterilizer/automated endoscopic reprocessor (AER)
- ❑ Cleaning instructions for scopes posted in cleaning area
- ❑ Copy of manufacturers' instructions for each cleaning product, disinfectant, high-level disinfectant, and designated test strips for the high-level disinfectant
- ❑ Appropriate personal protective equipment (PPE) available and used during processing- (Head/hair covering, mask/face shield, goggles, utility gloves, and fluid resistant gown)
- ❑ Flow of instruments is from dirty to clean with no cross-contamination (from clean to dirty or dirty to clean)
- ❑ Staff should know by the clearly designated location what stage of the HLD process a scope or instrument is in, whenever there is doubt if a step has been conducted or completed, reprocess the device (start over)
- ❑ Instruments, equipment, and supplies labeled "single use disposable" are not reprocessed or reused (ex. brushes)
- ❑ Written policies and procedures for HLD of scopes and probes are to include preventative maintenance and storage, must be current, and front-line staff must have knowledge of and access to these documents
- ❑ Competency evaluations should be completed for each employee on hire and considerations for annual review as recommended by evidence-based guidelines; also include random observations. Determine frequency of competency and training based on staff turnover, purchasing new equipment or products, or a breach in the process has been identified
- ❑ Processing log maintained: scope #, test strip results, immersion, initialed, and dated; may refer to and use HLD manufacturer provided log form

ENDOSCOPIC REPROCESSING

POINT-OF-USE

TRANSPORT

DECONTAMINATION

High-level Disinfection (HLD) – Manual Process:

- ❑ **Point-of-Use:** Scope immediately wiped down at point of use (in the procedure room) and channels flushed with enzymatic, detergent
- ❑ **Transport:** Scope is safely transported to the cleaning area/decontamination room in a leak-proof, puncture resistant container/device labeled as biohazardous which is based on evidence-based guidelines, manufacturer instructions for use
- ❑ **Decontamination:**
  - – Scope is leak tested; if fails, finish processing, remove from service, and send for repair
  - – All accessories are removed for cleaning or discarded if disposable – following manufacturer's instructions-for-use
  - – Scope and accessories immersed in measured enzymatic detergent
  - – Cleaning solution is changed after each scope is cleaned, based on manufacturer instructions for use
  - – All channels and accessories thoroughly brushed with manufacturer recommended brushes

- High Level Disinfectant (HLD) solution and concentration monitored and documented and dated as per manufacturer instructions for use
- If test strip fails while checking HLD minimum effective concentration, discard & replace HLD; if problem with test strips, use different bottle – always check expiration dates
- Test strips should be dated upon opening with the discard date as per manufacturer instructions for use, and quality control conducted per label instructions
- High-level disinfectant used is FDA-approved; used per label directions (contact time) all items completely submerged
- Temperature of the HLD meets HLD label instructions
- Soak time meets manufacturer's label instructions
- Scopes rinsed 3 times with sterile water or tap water as per manufacturer's instructions-for-use; flushed with alcohol and compressed air after high-level disinfection
- Scopes thoroughly dried before storage – there should be no staining at the base of the storage cabinet which may reflect an inadequate drying process; may consider reprocessing the scope
- Scopes vertically hung in a manner that prevents contamination; scope attachments are dried and stored separately
- Scopes reprocessed per evidence-based guidelines, manufacturer, and organizational policy

ENDOSCOPIC REPROCESSING

POINT-OF-USE

TRANSPORT

DECONTAMINATION

High-level Disinfection (HLD) – Using an Automated Endoscope Reprocessor (AER)

- **Point-of-Use:** Scope is immediately wiped down at point of use (procedure room) and channels flushed with enzymatic, detergent after procedure
- **Transport:** Scope is safely transported to the cleaning area/decontamination room in a leak-proof, puncture resistant container/device labeled as biohazardous which is based on evidence-based guidelines, manufacturer instructions for use
- **Decontamination:**
  - Leak test if AER doesn't do this; if fails, finish processing, remove from service, send for repair
  - Manual cleaning, brushing is performed
- HLD solution concentration is checked and documented; changed if test strip fails
- Test strips dated with discard date as per manufacturer instructions for use and quality control per label
- Scope connection instructions posted near the AER; proper connectors used
- Scope and accessories connected correctly to AER
- Cycle run, meets HLD contact time and temperature
- AER set for triple rinse in accordance with manufacturer's IFU
- On completion of cycle, if AER doesn't include a drying process, flush channels with alcohol and compressed air
- Scopes vertically hung in a manner that prevents contamination; scope attachments are dried and stored separately

PREVENT INFECTIONS

Recommendations to prevent infections in outpatient settings: **http://www.cdc.gov/HAI/settings/outpatient/checklist/outpatient-care-checklist-observations.html**

HLD Record Keeping – Sample Log Sheet for HLD Quality Monitoring

Date Test Strip Bottle First Opened: _____ Do Not Use After (Date): _____ Bottle Lot #: _____

QC Test Results: _____ QC Test Date: _____

Tested By (Initials): _____ Location/Dept: _____

Date Solution Opened	Date Solution Expires	Date Solution Tested	Time Solution Tested	Solution MEC Test Results (circle one)	Tested By (Initials)	Temp in ºF Before Use	Comments
				Pass Fail			

REVIEW QUESTIONS

Q&A

Q. **What is meant by "flow of instruments or devices," and in which direction should this always occur?**

A. The term "flow of instruments or devices" pertains to the cleaning of instruments; the flow is always from dirty to clean, with no risk of cross contamination.

Q. **What are the steps involved when decontaminating scopes using the manual HLD process?**

A. Scope is leak tested; if fails, follow manufacturer instructions for a failed leak test, remove from service, and send for repair.

- All accessories are removed for cleaning or discarded if disposable – following manufacturer's instructions-for-use
- Scope & accessories are fully immersed in measured enzymatic, detergent
- Cleaning solution changed after each scope is cleaned per manufacturer
- All channels and accessories thoroughly brushed with manufacturer brush(es)

Q. **When using an AER, how many rinses should scopes go through?**

A. The AER should be set for triple rinses based on manufacturer's instructions-for-use and evidence-based guidelines.

Important Takeaways

- **Become familiar with the Spaulding Classification and** understand which instruments or devices fall within the semi-critical category. When you know this and follow the manufacturer instructions for use, you will be able to determine which instruments/devices undergo HLD
- When transporting a "dirty" scope from the procedure room, always make sure that it is safely moved to the cleaning area/decontamination room in a leak proof, puncture resistant container/device labeled as biohazardous as per evidence-based guidelines
- Always change the cleaning solution after each scope. DON'T re-use the solution. When changing the solution always measure accurately, don't approximate

RESOURCES/LINKS

"2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities." (2008)

"2012 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes." *SGNA* (2012)

"2015 AORN Recommended Practices for Perioperative Nursing – Sterilization and Disinfection." *AORN* (2015)

- Disinfection – High-level
- Flexible Endoscopes – Cleaning and Processing

"2013 SGNA Guidelines for the Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes." *SGNA* (2013)

"Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." *ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013* (Consolidated Text)

"Chemical Sterilization and High-level Disinfection in Healthcare Facilities." • *ANSI/AAMI* ST58:2013 (2013)

"Flexible and Semi-rigid Endoscope Processing in Health Care Facilities." • *ANSI/AAMI* ST91:2015 (2015)

Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes: **http://www.sgna.org/Portals/0/Education/PDF/Standards-Guidelines/sgna_stand_of_infection_control_0812_FINAL.pdf**

Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes: **http://www.sgna.org/Portals/0/Education/PDF/Standards-Guidelines/SGNA_HLDGuideline13.pdf**

Statement on Reprocessing of Endoscopic Accessories and Valves: **http://www.sgna.org/Portals/0/Education/PDF/Position-Statements/Reprocessingvalvesdocument_FINAL.pdf**

The following links are provided courtesy of the International Association of Healthcare Central Service Material Management (IAHCSMM):

Immediately available: No Cost Resources. To access IAHCSMM educational materials: **www.iahcsmm.org/education/online-lessons.html**
(Please note: access to the articles is free; readers will need to pay a fee to take the associated CE exam.)

133 **Understanding Biofilm**
(Available until December 2016)

137 **Cleaning Complex Instruments**
(Available until August 2017)

The following links are provided courtesy of the Society of Gastroenterology Nurses and Associates (SGNA):

Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes (2013)

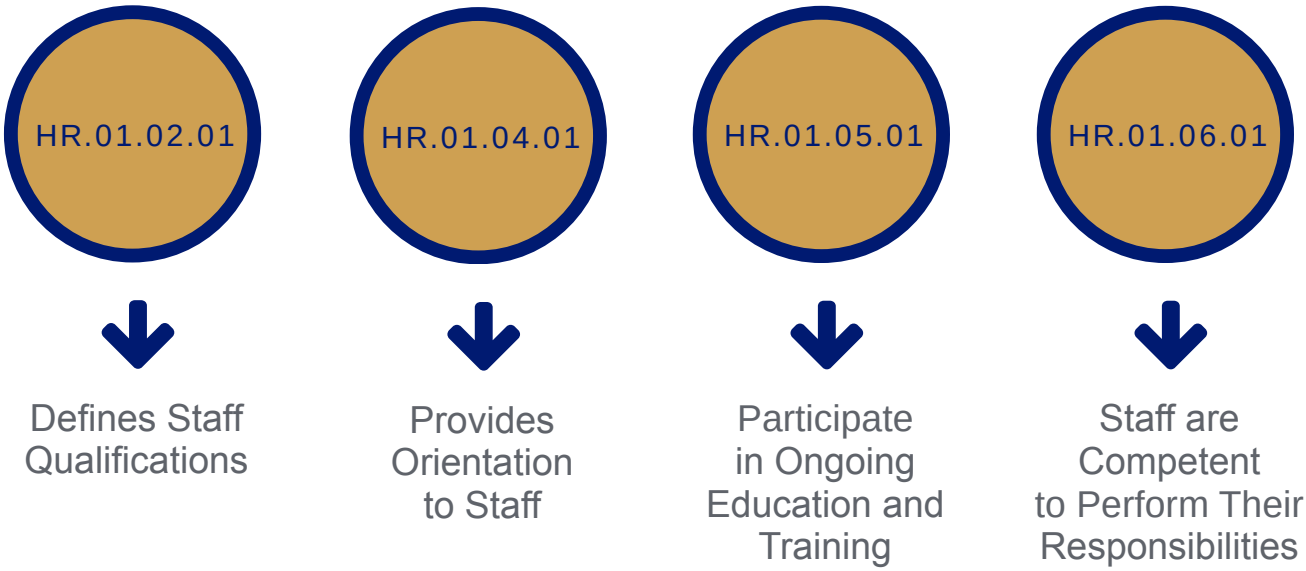
Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2012)

Statement on Reprocessing of Endoscopic Accessories and Valves (2014)

HR – Competency and Training

The Joint Commission®

Standards That Apply to HR – Competency and Training



RESPONSIBILITIES

- **High-level disinfection and sterilization –** complex processes (with multiple important steps) that require front-line staff and those responsible for its oversight to be competent and trained initially and on an ongoing basis as defined by the organization
- **Training and competencies –** to be documented and maintained in the employee record or file
- **New products, devices, and equipment –** continually being added along with new front-line staff, supervision, and services. It is critical to the positive outcome of a patient's procedure that instruments are sterilized and endoscopes and probes are high-level disinfected (as recommended by the device manufacturer and evidence-based guidelines)

REVIEW QUESTIONS

Q&A

Q. **How often should front-line staff and supervisors responsible for HLD and sterilization processes receive training in order to maintain their competency status?**

A. They must be trained initially and on an ongoing basis at least every three years, or as defined by organizational policy, law, and regulation.

Q. **Where should training records of individual staff members be stored?**

A. Records documenting a staff member's and supervisor's training and competency must be stored in their employee record or file.

Q. **Why must instruments be sterilized and endoscopes and probes undergo HLD procedures, as recommended by the device manufacturer and evidence-based guidelines?**

A. This is done in order to insure the positive outcome of a patient's procedure to minimize the risk of transmitting an infectious agent to the patient.

Important Takeaways

- HLD and sterilization are complex processes that require front-line staff and those responsible for its oversight to be competent and trained not only initially, but on an **ongoing basis as defined by the organization.**
- Records documenting a staff member's training and competency must be stored in their employee record **or file.**
- It is critical to the positive outcome of a patient's procedure that instruments are sterilized and endoscopes and probes are high-level disinfected (as recommended by the device manufacturer and evidence-based guidelines).

RESOURCES/LINKS

"2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities." Centers for Disease Control and Prevention (2008)

"2012 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes." *SGNA* (2012)

"2015 AORN Recommended Practices for Perioperative Nursing – Sterilization and Disinfection." *AORN* (2015)

- Disinfection – High-level
- Flexible Endoscopes – Cleaning and Processing

"2013 SGNA Guidelines for the Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes." *SGNA* (2013)

Association for Professionals in Infection Control. *APIC Text of Infection Control and Epidemiology. 4th Edition.* 2014. Print:

- Chapter 31 Cleaning, Disinfection, and Sterilization
- Chapter 55 Endoscopy
- Chapter 106 Sterile Processing

"CDC Patient Notification Toolkit." CDC. Web. 2013.
http://www.cdc.gov/injectionsafety/pntoolkit/index.html?utm_One+%26+Only+Campaign%3A+CDC+Releases+Patient+Notification+Toolkit&utm_campaign=patient+notification+toolkit&utm_medium=email
"This toolkit is intended to be used after a healthcare facility or health department has made the decision to conduct a patient notification."

"Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." *ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 (Consolidated Text)*

"Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes (2011)." *American Society for Gastrointestinal Endoscopy (ASGE) (2011).*

"Chemical Sterilization and High-level Disinfection in Healthcare Facilities." • *ANSI/AAMI* ST58:2013 (2013)

"Flexible and Semi-rigid Endoscope Processing in Health Care Facilities." • *ANSI/AAMI* ST91:2015 (2015)

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www.iahcsmm.org/education/online-lessons.html
(Please note: access to the articles is free; readers will need to pay a fee to take the associated CE exam.)

140 **Leadership Skills for New Central Service Supervisors**
(Available until February 2018)

607 **Education and Training Procedures for Central Service Personnel**
(Available until February 2018)

Appendix – Standards

The Joint Commission®

Standards Relating to HLD and/or Sterilization Processes

IC.01.01.01
The organization assigns responsibility for the daily management of infection prevention and control activities.

IC.01.03.01
Requires organizations to identify risks for acquiring and transmitting infections.

IC.01.05.01
The organization has an infection prevention and control plan.

IC.02.01.01
The hospital implements its infection prevention and control plan.

IC.02.02.01
The organization reduces or eliminates the risk of infections associated with medical equipment, devices, and supplies.

IC.02.03.01
The organization works to prevent the transmission of infectious disease among patients, licensed independent practitioners, and staff.

IC.03.01.01
The organization evaluates the effectiveness of its infection prevention and control plan annually and whenever risks significantly change.

HR.01.02.01
The organization's leaders allocate needed resources for the infection prevention and control program.

HR.01.04.01
The hospital orients its staff to the key safety content before staff provides care, treatment, and services. Completion of this orientation is documented.

HR.01.05.03
Staff participate in ongoing education and training.

HR.01.06.01
Staff are competent to perform their responsibilities.

LD.01.03.01 – OBS (Office-Based Surgery Setting)
Practice leaders are ultimately accountable for the safety and quality of care, treatment, or services.

LD.01.03.01 – Hospital (HAP)
The governing body is ultimately accountable for the safety and quality of care, treatment, and services.

LD.01.03.01 – Ambulatory (AMB)
Governance is ultimately accountable for the safety and quality of care, treatment, or services.

LD.01.03.01 – Critical Access Hospitals (CAH)
The governing body is ultimately accountable for the safety and quality of care, treatment, and services.

LD.03.01.01 – OBS (Office-Based Surgery Setting)
Leaders create and maintain a culture of safety and quality throughout the practice.

LD.03.01.01 – Hospital (HAP)
Leaders create and maintain a culture of safety and quality throughout the hospital.

LD.03.01.01 – Ambulatory (AMB)
Leaders create and maintain a culture of safety and quality throughout the organization.

LD.03.01.01 – Critical Access Hospitals (CAH)
Leaders create and maintain a culture of safety and quality throughout the critical access hospital.

LD.03.03.01 – OBS (Office-Based Surgery Setting)
Leaders use practice-wide planning to establish structures and processes that focus on safety and quality.

LD.03.03.01 – Hospital (HAP)
Leaders use hospitalwide planning to establish structures and processes that focus on safety and quality.

LD.03.03.01 – Ambulatory (AMB)
Leaders use organizationwide planning to establish structures and processes that focus on safety and quality.

LD.03.03.01 – Critical Access Hospitals (CAH)
Leaders use critical access hospitalwide planning to establish structures and processes that focus on safety and quality.

LD.03.06.01 – OBS (Office-Based Surgery Setting)
Those who work in the practice are focused on improving safety and quality.

LD.03.06.01 – Hospital (HAP)
Those who work in the hospital are focused on improving safety and quality.

LD.03.06.01 – Ambulatory (AMB)
Those who work in the organization are focused on improving safety and quality.

LD.03.06.01 – Critical Access Hospitals (CAH)
Those who work in the critical access hospital are focused on improving safety and quality.

LD.04.01.05
The organization effectively manages its programs, services, sites, or departments.

LD.04.01.11
The organization makes space and equipment available as needed for the provision of care, treatment, and services.

EC.02.04.03
The organization inspects, tests, and maintains medical equipment.

EC.02.05.01
The organization manages risks associated with its utility systems.

NPSG.07.01.01
Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

NPSG.07.03.01
Implement evidence-based practices to prevent health care–associated infections due to multidrug-resistant organisms in acute care hospitals.

NPSG.07.05.01
Implementing evidence-based practices for preventing surgical site infections.