KDHE-KHC Infection Prevention Learning Action Network for Outpatient Settings

Session 7 — May 20, 2021

Device Reprocessing

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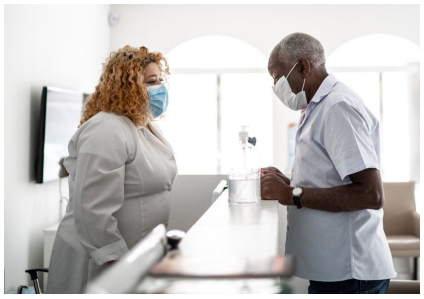
KDHE-KHC Learning Action Network



February 25	IP Program Development
March 11	Surveillance and Reporting
March 25	Occupational Health
April 8	Personal Protective Equipment
April 22	Hand Hygiene
May 6	Environmental Cleaning & Disinfection
May 20	**Device Reprocessing**
June 3	Antimicrobial Stewardship
June 17	Bringing It All Together

Recordings and handouts are available online. Visit www.khconline.org/LAN

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Feedback Summary from Previous Session

Session #6: Environmental Cleaning and Disinfection

The most useful thing presented included:

- Reapply product if dwell time not met
- Reminders for staff to know where to find dwell time
- Explaining the difference between cleaning and disinfection, Wet times, Indoor Air Quality definition, temp and humidity impact

Next steps identified by participants:

- Share will all staff
- Checking Manufacturer IFUs for specific medical equipment and devices
- Re-educate staff on where to find IFUs
- Buying a fluorescent marker and black light
- Complete formal and informal education on disinfection of medical devices
- Ensure my new IPs can apply the information taught
- Re-educate staff on where to find dwell time
- Evaluating the cleaners used

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Session #7: Device Reprocessing

Presenter

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Session #7: Device Reprocessing

Session Objectives

- Explore the fundamental role of Infection Preventionist (IP) in device reprocessing in the outpatient setting
- Describe the role of the IP in identifying device reprocessing gaps through audits
- Review top 10 High Level Disinfection strategies for success
- Describe ways to facilitate safe sterilization in the outpatient setting

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Polling Question #1

Have you been involved or responsible for implementing HLD/sterilization practices within your facility?

- ❑ Yes
- ❑ No

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Polling Question #2

In what setting did you implement HLD/sterilization workflow?
(select all that apply)

- ❑ Hospital
- ❑ Physician office/clinic
- ❑ Surgical center
- ❑ Dental office
- ❑ Long-term care
- ❑ Other (type in chat)

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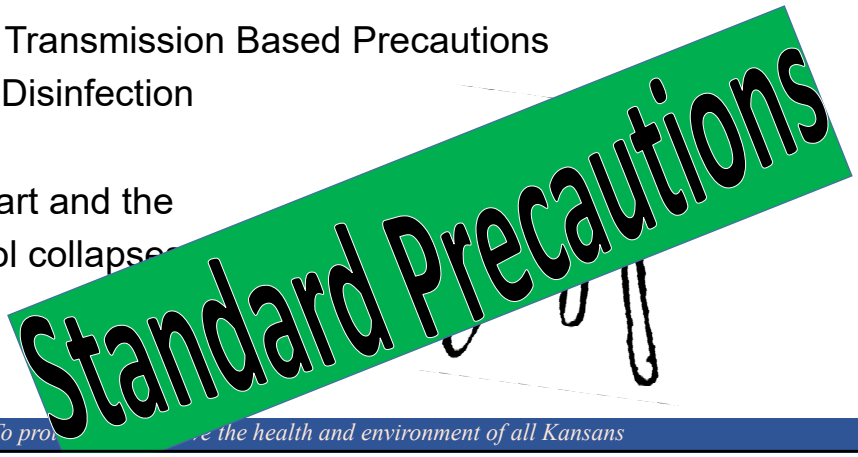
Infection Prevention Basics

"**PREVENTION** stool"

1. Hand hygiene
2. Standard & Transmission Based Precautions
3. Cleaning & Disinfection

Remove any part and the prevention stool collapse



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Core Practices: Standard Precautions

- Hand hygiene
- Environmental Cleaning and Disinfection
- Injection and medication safety
- Appropriate use of Personal Protective Equipment
- Minimizing potential exposures for example respiratory hygiene & cough etiquette
- Reprocessing of reusable medical equipment

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Device Reprocessing

As the continuum of care continues to expand to include a growing number of diagnostic and therapeutic cares in the outpatient/ambulatory areas—so must our ability to safely clean, disinfect and sterilize instruments/devices in these areas.

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Spaulding Classification

To determine the level of disinfection that should be applied to an instrument or device after use. The level of cleaning/disinfection or sterilization will be determined by intended use.

- Critical devices: contact sterile tissues or body cavities or the bloodstream and should be sterilized.
- Semi-critical devices: contact mucous membranes or non-intact skin and minimally require high level disinfection.
- Non-critical devices: contact healthy, intact skin and minimally require low level disinfection.

Patient Contact	Device Classification	Examples	Reprocessing
Intact skin	**Non-critical**		Low-level disinfection; Intermediate-level disinfection
Mucous membranes; Non-intact skin	**Semi-critical**		High-level disinfection
Sterile areas of the body; Vascular system	**Critical**		Sterilization

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Staying in the know…"IP" or is it "PI"

Leadership must know:

- All locations where HLD/sterilization is conducted
  - Ensure reprocessing in being performed incongruence with manufacturer's recommendation (IFU) and organizations policies and procedures
- How all scopes, probes and devices requiring HLD/sterilization are reprocessed
  - Clinics (ENT, Urology, OB), ERs, ICUs, Sleep Center etc.
  - Partner with Biomedical Engineering to assist with locating equipment

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Gap Analysis
Risk Assessments

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Gap Analysis/Risk Assessment

Proactively evaluate risk associated with processes/workflow

- Storage
  - HLD /sterilized
- Point of use cleaning
- Current reprocessing methods
  - Onsite reprocessing
  - Sterile Processing
- Manufacturers reprocessing recommendations/best practices
- Transportation process
- Air exchanges/ventilation
- Chemical disposal practices

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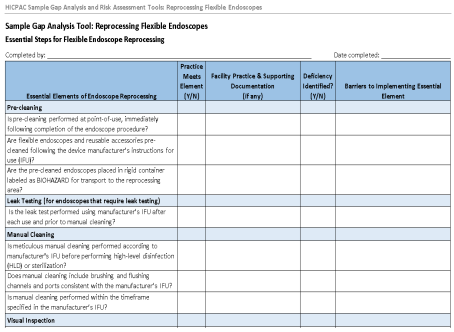
Stay in the know…Don't let bugs grow!

Sample tools: HICPAC GAP Analysis & Risk Assessment



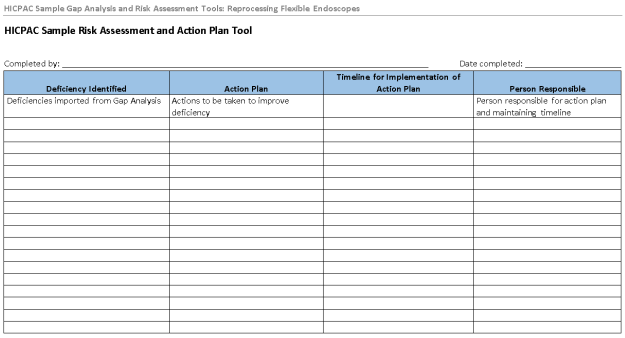
HICPAC Sample Gap Analysis and Risk Assessment Tools: Reprocessing Flexible Endoscopes

Sample Gap Analysis Tool: Reprocessing Flexible Endoscopes

Essential Steps for Flexible Endoscope Reprocessing

Completed by: _____ Date completed: _____

Essential Elements of Endoscope Reprocessing	Practice Meets Element (Y/N)	Facility Practice & Supporting Documentation (if any)	Deficiency Identified? (Y/N)	Barriers to Implementing Essential Element
Pre-cleaning				
Is pre-cleaning performed at point-of-use, immediately following completion of the endoscope procedure?				
Are flexible endoscopes and reusable accessories pre-cleaned following the device manufacturer's instructions for use (IFU)?				
Are the pre-cleaned endoscopes placed in rigid container labeled as BIOHAZARD for transport to the reprocessing area?				
Leak Testing (for endoscopes that require leak testing)				
Is the leak test performed using manufacturer's IFU after each use and prior to manual cleaning?				
Manual Cleaning				
Is meticulous manual cleaning performed according to manufacturer's IFU before performing high-level disinfection (HLD) or sterilization?				
Does manual cleaning include brushing and flushing channels and ports consistent with the manufacturer's IFU?				
Is manual cleaning performed within the timeframe specified in the manufacturer's IFU?				
Visual Inspection				



HICPAC Sample Gap Analysis and Risk Assessment Tools: Reprocessing Flexible Endoscopes

HICPAC Sample Risk Assessment and Action Plan Tool

Completed by: _____ Date completed: _____

Deficiency Identified	Action Plan	Timeline for Implementation of Action Plan	Person Responsible
Deficiencies imported from Gap Analysis	Actions to be taken to improve deficiency		Person responsible for action plan and maintaining timeline

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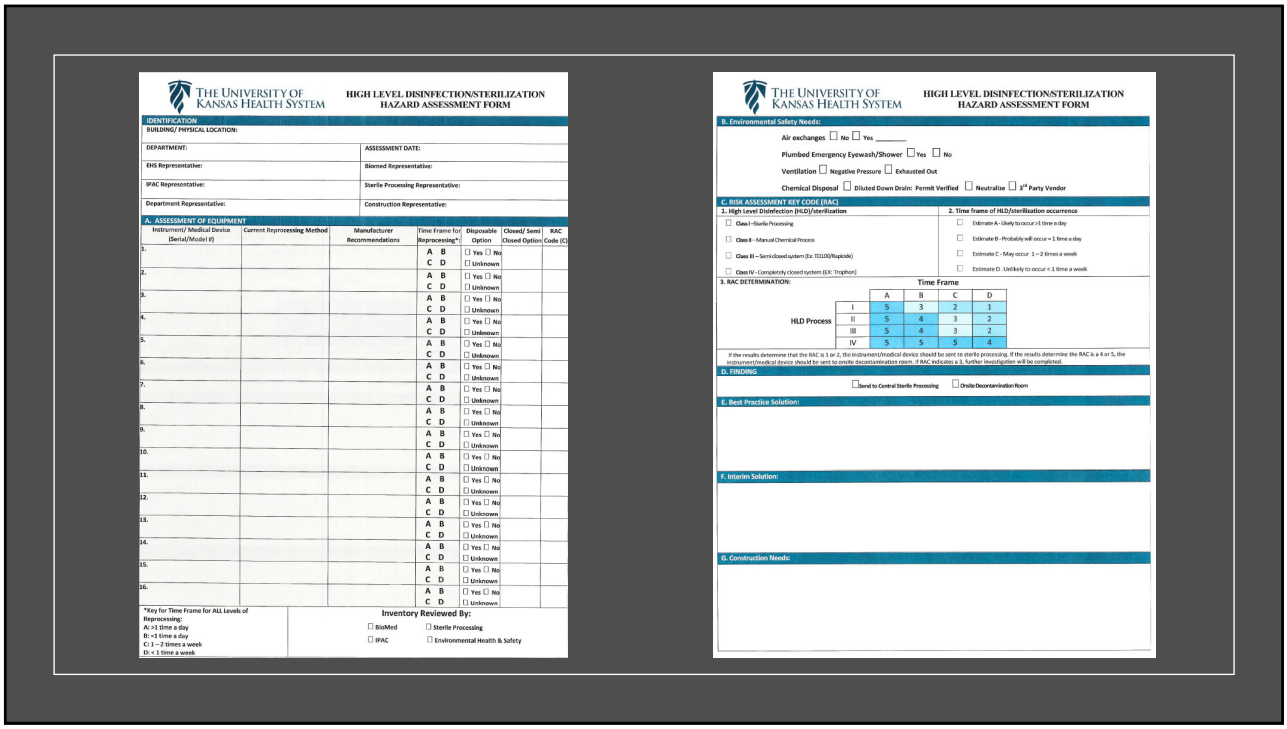

THE UNIVERSITY OF KANSAS HEALTH SYSTEM

HIGH LEVEL DISINFECTION/STERILIZATION HAZARD ASSESSMENT FORM

IDENTIFICATION

BUILDING/ PHYSICAL LOCATION:

DEPARTMENT:	ASSESSMENT DATE:
EHS Representative:	Biomed Representative:
IPAC Representative:	Sterile Processing Representative:
Department Representative:	Construction Representative:

A. ASSESSMENT OF EQUIPMENT

Instrument/ Medical Device (Serial/Model #)	Current Reprocessing Method	Manufacturer Recommendations	Time Frame for Reprocessing*	Disposable Option	Closed/ Semi Closed Option	RAC Code (C)
1.			A B C D	☐ Yes ☐ No ☐ Unknown		
2.			A B C D	☐ Yes ☐ No ☐ Unknown		
3.			A B C D	☐ Yes ☐ No ☐ Unknown		
4.			A B C D	☐ Yes ☐ No ☐ Unknown		
5.			A B C D	☐ Yes ☐ No ☐ Unknown		
6.			A B C D	☐ Yes ☐ No ☐ Unknown		
7.			A B C D	☐ Yes ☐ No ☐ Unknown		
8.			A B C D	☐ Yes ☐ No ☐ Unknown		
9.			A B C D	☐ Yes ☐ No ☐ Unknown		
10.			A B C D	☐ Yes ☐ No ☐ Unknown		
11.			A B C D	☐ Yes ☐ No ☐ Unknown		
12.			A B C D	☐ Yes ☐ No ☐ Unknown		
13.			A B C D	☐ Yes ☐ No ☐ Unknown		
14.			A B C D	☐ Yes ☐ No ☐ Unknown		
15.			A B C D	☐ Yes ☐ No ☐ Unknown		
16.			A B C D	☐ Yes ☐ No ☐ Unknown		

*Key for Time Frame for ALL Levels of Reprocessing:
A: >1 time a day
B: <1 time a day
C: 1 – 2 times a week
D: < 1 time a week

Inventory Reviewed By:
☐ BioMed ☐ Sterile Processing
☐ IPAC ☐ Environmental Health & Safety

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HIGH LEVEL DISINFECTIONSTERILIZATION HAZARD ASSESSMENT FORM

B. Environmental Safety Needs:

Air exchanges ☐ No ☐ Yes _____

Plumbed Emergency Eyewash/Shower ☐ Yes ☐ No

Ventilation ☐ Negative Pressure ☐ Exhausted Out

Chemical Disposal ☐ Diluted Down Drain: Permit Verified ☐ Neutralize ☐ 3rd Party Vendor

C. RISK ASSESSMENT KEY CODE (RAC)

1. High Level Disinfection (HLD)/sterilization

- ☐ Class I–Sterile Processing
- ☐ Class II – Manual Chemical Process
- ☐ Class III – Semi-closed system (Ex: TOLOO/Rapicide)
- ☐ Class IV - Completely closed system (EX: Trophon)

2. Time frame of HLD/sterilization occurrence

- ☐ Estimate A - Likely to occur >1 time a day
- ☐ Estimate B - Probably will occur < 1 time a day
- ☐ Estimate C - May occur 1 – 2 times a week
- ☐ Estimate D - Unlikely to occur < 1 time a week

3. RAC DETERMINATION:

HLD Process	Time Frame A	B	C	D
I	5	3	2	1
II	5	4	3	2
III	5	4	3	2
IV	5	5	5	4

If the results determine that the RAC is 1 or 2, the instrument/medical device should be sent to sterile processing. If the results determine the RAC is a 4 or 5, the instrument/medical device should be sent to onsite decontamination room. If RAC indicates a 3, further investigation will be completed.

D. FINDING

☐ Send to Central Sterile Processing ☐ Onsite Decontamination Room

E. Best Practice Solution:

F. Interim Solution:

G. Construction Needs:

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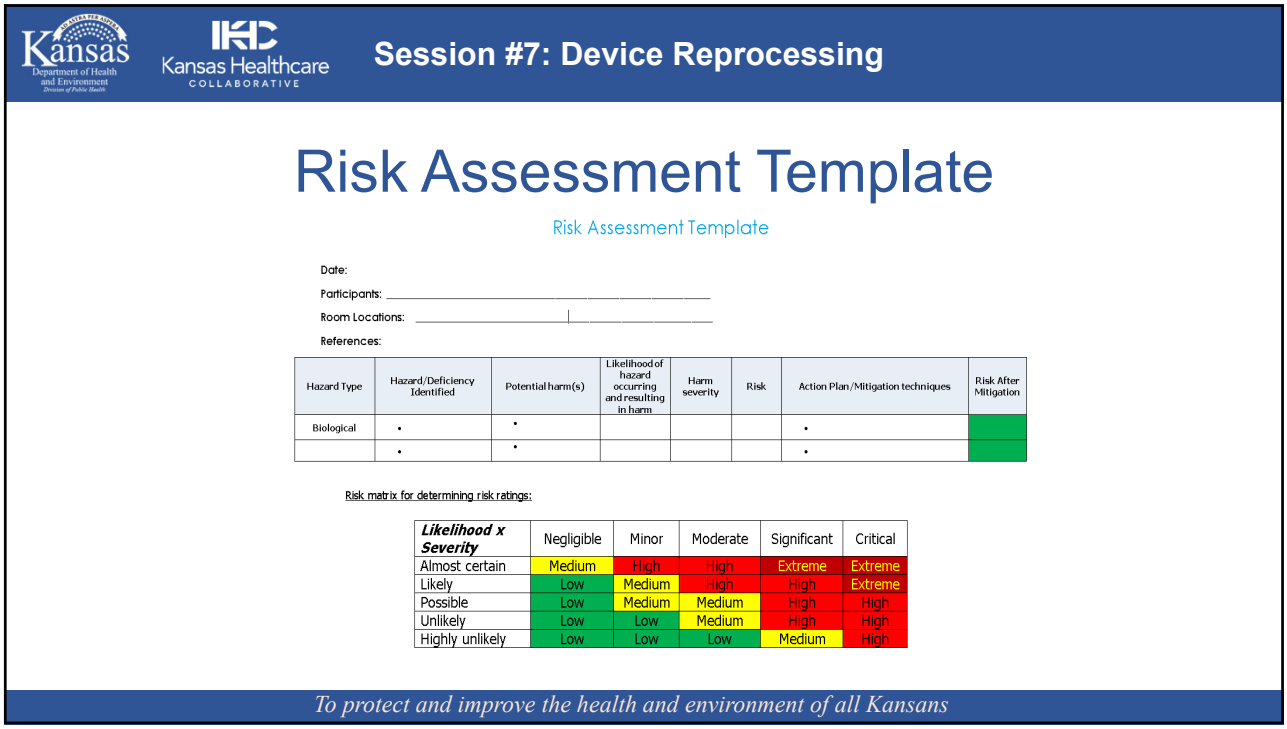

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Risk Assessment Template

Risk Assessment Template

Date:

Participants: _____

Room Locations: _____

References:

Hazard Type	Hazard/Deficiency Identified	Potential harm(s)	Likelihood of hazard occurring and resulting in harm	Harm severity	Risk	Action Plan/Mitigation techniques	Risk After Mitigation
Biological	•	•				•	
	•	•				•	

Risk matrix for determining risk ratings:

Likelihood x Severity	Negligible	Minor	Moderate	Significant	Critical
Almost certain	Medium	High	High	Extreme	Extreme
Likely	Low	Medium	High	High	Extreme
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Low	Medium	High	High
Highly unlikely	Low	Low	Low	Medium	High

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Device Reprocessing

- Equipment locations
- Completed gap analysis
- Completed risk assessment
  - Implementing individual action plans to improve practice
- Start quality assurance monitoring

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Evidence-Based Guidelines

- ANSI/AAMI ST 91: Flexible and semi-rigid endoscope processing in health care facilities
- ANSI/AAMI ST 58: Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST 79: Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- 2021 Multi-society guideline on reprocessing flexible GI endoscopes and accessories
- CDC/HICPAC Guideline for disinfection and sterilization in healthcare facilities
- The Joint Commission high-level disinfection and sterilization booster pak

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HLD Training & Competency

Training should be performed	Competency	Manufacturer instructions for use (IFU)
• Upon hire and prior to taking on HLD reprocessing responsibilities • Annually and when new devices are introduced • By competent person (IP Nurse, Education Specialist)	• Must be verified prior to performing reprocessing • Records are maintained for each employee, including managers, supervisors and infection preventionists	• Must be up to date/current • Reviewed regularly, they may change over time • Readily accessible in the area where the device is being reprocessed

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Competency: HLD Courses

- 7 HLD Courses
  - Rapicide PA
  - OPA
  - TD 100
  - Trophon EPR
  - Trophon 2
  - Endoscope Reprocessing
  - ASTRA VR

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HLD Documentation

- Should be standardized across the organization, and should include the minimum:
  - Two patient identifiers (name/MRN)
  - Date
  - Device identifier
  - MEC/MRC (timer)
  - Temperature
  - Soak time/rinse time
  - Name of person performing HLD
  - Reuse life

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HLD Sample Documentation Form

Manual Non-Scope OPA High Level Disinfection Procedures

Date	Patient name, Medical record number	Manufacturer expiration date on OPA primary container does not exceed current date	75 day expiration date on opened OPA primary container recorded and does not exceed current date	14 day expiration date on OPA secondary soaking container and does not exceed current date	Manufacturer expiration date on test strip bottle does not exceed current date	90 day expiration date on opened test strip bottle and does not exceed current date	OPA solution in secondary soaking container with a minimum temperature of 20° C (68° F)	Instrument has been cleaned / decontaminated with enzymatic cleaner prior to disinfection	OPA is at Minimum Effective Concentration (MEC) 90 seconds after submerging test strip in solution	MEC read at 90 seconds + Pass/- Fail		Type of Instrument	Soak Start Time	Soak End Time	3 separate 1 minute rinse			Performed by
															1	2	3	
5/1/2021	Patient Name, 1234567	✓	✓	✓	✓	✓	✓	✓	✓	✓		Rhino #4	0940	0952	✓	✓	✓	JJ

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Audits/Tracers

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Quality Assurance Audits/Tracers

- Audits should be conducted in all areas where reprocessing occurs
  - Can be very difficult in large facilities or systems, often do not know where reprocessing is occurring
    - Geographical locations
    - Lack of resources
- Regularly audit the adherence to all reprocessing steps, from pre-clean to storage
  - SPD audits
  - HLD audits
- Provide feedback to personnel/department managers on audit findings
  - Ensure practice is congruent with policy/procedure

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HLD Quality Assurance Tracer

- Section: General Observations
- Section: Pre-Cleaning
- Section: Documentation
- Section: Hang Time/Storage
- Section: POU Cleaning, Transportation & Leak Testing
- Section: Documentation Trophon devices
- Section: Staff Interview ASTRA VR only
- Section: Staff Interview for TD 100 only
- Section: Staff Interview for OPA/Resert only
- Section: Staff interview for Rapicide PA

Section: General Observations

1	Thermometer and timer available and not expired
2	PPE available? (gloves, face mask/eye protection, impervious gown when reprocessing equipment)
3	Standardized spill kit and appropriate neutralizer available
4	Eye wash station present (if applicable) and weekly documentation is complete?

Section: Hang Time/Storage

12	Stored scopes do not exceed designated hang time
13	Equipment is stored in a manner that prevents inadvertent contamination and facilitates drying
14	Scope(s)/probe(s) are free hanging in a designated storage area.
15	Scope(s)/probe(s) storage cabinet are clean and free of dust.
16	Staff Interview: How often do you wipe out the scope/probe storage cabinet (weekly)?

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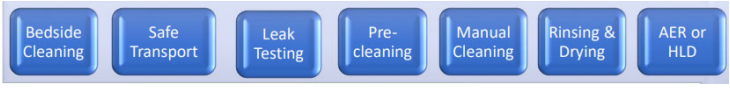
Top 10 HLD Strategies for Success

1. Ensure staff are trained and competent
   a) Managers and frontline staff
2. Appropriate PPE is donned/doffed
3. Environmental Controls
   a) Negative pressure (decontamination area)
   b) Dirty to clean workflows
   c) Eyewash stations (corrosive chemicals)
4. Medical equipment is cleaned at the point of use
   a) Includes interior/exterior portions of the scope (mfg. recommendations)
   b) Ensure instrument compatibility



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Top 10 HLD Strategies for Success (cont'd)

5. Proper Transportation
   a) Leakproof, puncture resistant container
   b) Labeled biohazard symbol
6. Leak Testing/Mechanical Cleaning
   a) Perform leak test
   b) Proper dilution, temperature, soak time
   c) *Extended processing time if necessary
   d) Cleaning Verification
7. High Level Disinfection Process
   a) Exposure time, proper immersion/priming of channels, MRC/MEC checks, temperature, rinse

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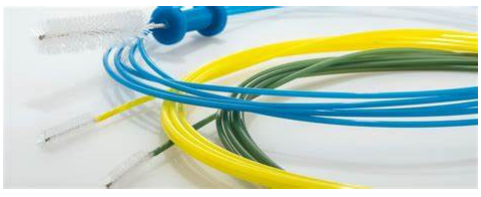
Top 10 HLD Strategies for Success (cont'd)

8. Drying & Storage
   a) Drying cabinet
   b)10 minutes of forced medical grade air
   c) Equipment is stored in a manner that prevents inadvertent contamination
9. HLD QA/QI Program
   a) HLD traceability—documentation
      a) Cycle print outs, test strip results & QC test
   b) Auditing/Tracers
10. Transition from HLD to sterilization when possible

Few additional tidbits:

- Brushes (reusable/disposable)
  - Appropriate size
  - Clean/disinfect (mfg. recommendation)
- Automated Endoscope Reprocessor (AER)
  - Attach appropriate connectors
  - Routine maintenance (filters/line disinfection)



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Facilitating Safe Sterilization in Outpatient Setting

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Sterilization in Ambulatory/Outpatient Setting

- Performing complex procedures
- Patient throughput is rapid
- Equipment: Stainless-steel instruments, speculums, scopes (Yikes!)
- Staff lack sterilization experience
  - Nurse, CNAs or technicians reprocess equipment
- Inadequate infrastructure

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Issues…Issues…Issues ☹

- Inadequate space & ventilation (infrastructure)
- Sterile storage requirements
- Biological indicators (BIs)
- Chemical indicators(CIs)

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Few New Standards in town (Option 1)

- Experienced liaisons (IP or SPD) assess clinics/processing functions
- Develop standards of care
  - Indicators (internal/external)
    - BIs
  - POU cleaning
  - Safe transportation methods
  - Appropriate storage
  - Specific cycle parameters
  - Preventative Maintenance of tabletop sterilizers

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New Standard (Option #2)

- Centralization of sterile processing practices
  - Multi-disciplinary approach
    - IPAC
    - Organizational leadership
    - Sterile Processing
    - Capital Operations
  - Need to double/triple fleet of instruments
    - Large investment up front
      - Pay off safer standardized reprocessing
      - Trained, certified technicians

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Comprehensive Approach

1. Inspire and activate leadership
2. Review & assess current state
3. Evaluate
4. Make recommendations and follow up

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Partner to Prevent Infections

Sterile Processing Partners

- Lean on their expertise and best practices
- Align processes with ANSI/AAMI standards
- Become familiar with manufacturer's recommendations
- Tour areas with SPD leaders/educators and unit leadership
- Develop auditing processes specific to sterilization process

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Session #7 Quiz

Which one of following elements is <u>not</u> an integral part of implementing a High-Level Disinfection program?

- ❑ Training (upon hire & annually)
- ❑ HLD Super-users
- ❑ Competency (demonstration, clinical observation or verbalization)
- ❑ Manufacturer instructions for use (readily accessible)

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Resources/References

- HICPAC Sample Gap Analysis and Risk Assessment Tools: Reprocessing Flexible Endoscopes. https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html
- 2021 Multi-society guideline on reprocessing flexible GI endoscopes and accessories. Multi-society guideline on reprocessing flexible GI endoscopes and accessories (giejournal.org)
- The Joint Commission high-level disinfection and sterilization booster pak. tjc_hld_boosterpakpdf.pdf (jointcommission.org)
- ANSI/AAMI ST 91: Flexible and semi-rigid endoscope processing in health care facilities
- ANSI/AAMI ST 58: Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST 79: Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- CDC/HICPAC Guideline for disinfection and sterilization in healthcare facilities https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

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References

Rutala WA; Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for disinfection and sterilization in healthcare facilities. 2008.

Lukejohn, D, Raman, M, et al. Multi-society guideline on reprocessing flexible GI endoscopes and accessories. Gastrointestinal Endoscopy 2021; 93: 11-33.

Luebbert Prinz, P. Top Ten Sterilization Issues in an Ambulatory Surgery Center. http://multimedia.3m.com/mws/media/662112O/sterilization-issues-in-ambulatory-ctrs-healthvie-5-10.pdf

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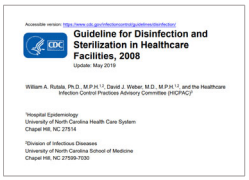
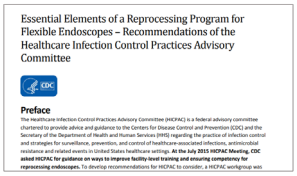
Next steps

- ❑ Review these three resources:

1. CDC HICPAC Guideline for Disinfection and sterilization in Healthcare Facilities (2008)
   https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf
2. HICPAC Sample Gap Analysis and Risk Assessment Tools: Reprocessing Flexible Endoscopes.
   https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html
3. 2021 Multi-society guideline on reprocessing flexible GI endoscopes and accessories (giejournal.org)
   https://www.giejournal.org/action/showPdf?pii=S0016-5107%2820%2934851-3


Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008


Multisociety guideline on reprocessing flexible GI endoscopes and accessories


Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee

Preface

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Q&A

Please type your questions or comments in the chat.

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KDHE-KHC Infection Prevention LAN for Outpatient Settings

Upcoming Sessions

June 3 Antimicrobial Stewardship

June 17 Bringing it all together (1 hour)

Recordings and handouts of past sessions can be located here:

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KDHE-KHC Infection Prevention LAN

Questions?

Contact:

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