Flexible Endoscope Reprocessing:

Today's Common Gaps, Tomorrow's Challenges & Future Considerations

A presentation for HealthTrust Members
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Disclosure and Conflict of Interest

Melissa Kubach is employed by Mobile Instrument Service & Repair as a National Specialty Education Coordinator

Objectives:

At the end of this session, attendees will:

1. Identify the common gaps associated with reprocessing flexible endoscopes.
2. Discuss future changes that may affect departments that reprocess flexible endoscopes.
3. Compare and contrast the benefits of emerging flexible endoscope technology.

Current Gaps affecting Reprocessing Success

PRE-CLEANING IS NOT JUST FOR THE GI:

Operating Room compliance remains a challenge!

- Pre-clean immediately after use
- Removal of gross debris for both the external surface and internal channel lumens
- Lapses may make debris removal difficult to impossible
- Increased risk of biofilm development

Barriers affecting OR Pre-cleaning completion:

- Cleaning is difficult and messy
- Post op patient care is the first priority
- Endoscope is not used for the majority of the case
- Perception that cleaning should be done only in the cleaning room
- Lack of understanding the cleaning requirements

Delay of Cleaning

Reduce risk and prove that endoscopes are not falling into delayed cleaning scenarios

- Good documentation
- Simple solutions
- SPD challenges
- Frequent offenders

Visual Inspection Completion with Documentation

Documentation

Visual inspection completion with documentation-

- If you inspect it; document it!
- Damage is very common and not often noticed with the naked eye

Understanding your AER Cleaning Claims

Which steps are excluded?

Does this apply to all models?

What does my recommending organization say?

Is my policy aligned?

Do I have documentation support?

Advance Cleaning Claims

Allows for the elimination of:

Suctioning

Flushing

Rinsing

Release

Manual Cleaning

Testing

Policy

Standards & Recommendations

Supporting organizations & documentation:

- The 510K claim exemption statement from the AER manufacturer is usually not present in facilities that are audited
- FDA, SGNA & AAMI does not support the excluding of any flexible endoscope manufacturer IFU cleaning steps

ERCP/EUS Flexible Scopes

If your department performs ERCP procedures or EUS Linear procedures that have an exposed elevator wire there should be no exclusion of any manual cleaning steps.

Communication

FDA Supplemental Instructions

- How do you keep updated?
- Establish a formal path of communication

The Latest on Drying of High-Level Disinfected Flexible Endoscopes:

Drying of Endoscopes

- Dried externally
- Extended internal drying
- Cabinet positive pressure or circulated filtered air
- Cabinets that facilitate drying

“After a careful evaluation of high-level disinfection (HLD) and sterilization process steps, The Joint Commission has refined its scoring as of September 1, (2019) to focus on the process steps that pose the highest risk to patients if they fail.

Last year, 72 percent of surveyed hospitals and critical access hospitals were found to be noncompliant with The Joint Commission’s high-level disinfection and sterilization standard IC.02.02.01. We are refining some of the scoring guidelines to clarify expectations.

“Dry Endoscopes Before Storing

Recent articles have indicated that a key component of ensuring that microorganisms do not replicate during storage is careful drying – not the duration of storage. Surveyors will check for compliance with manufacturers’ instructions for drying scopes, but will no longer score any finding related to hang time unless a reprocessing frequency has been specified by the endoscope manufacturer and is not followed.”[1]

Handling of Contaminated Endoscopes Within Sterile Processing Department

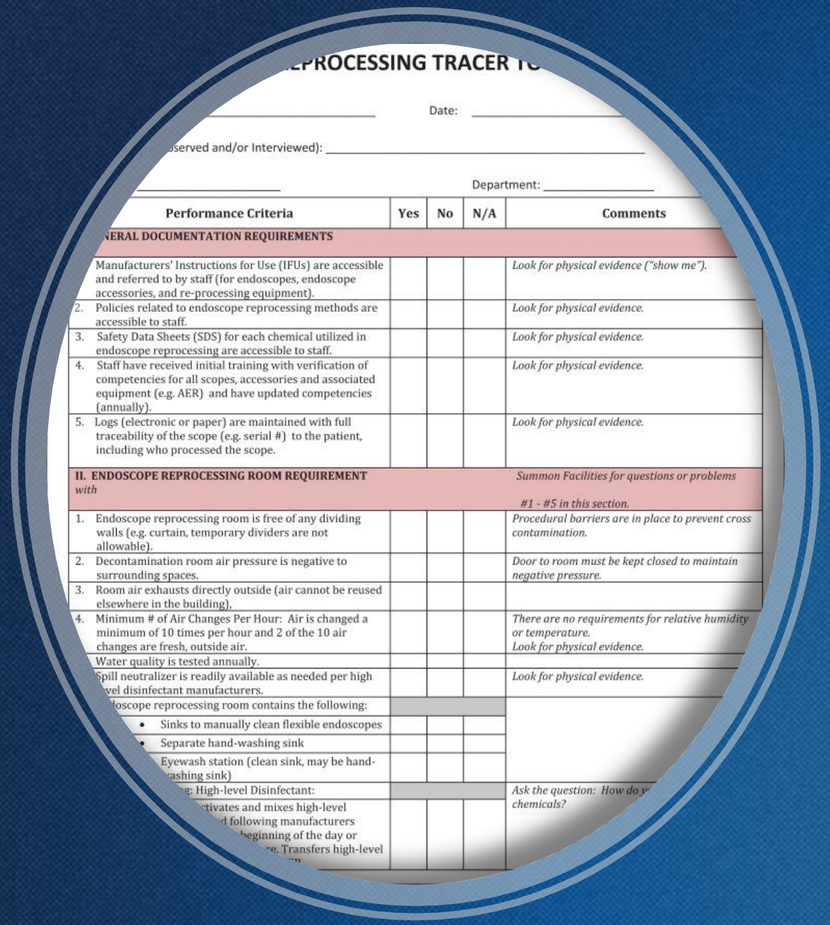
No QUATS

- Designed for hard, non-porous surfaces only
- Flexible endoscope materials may retain chemical residuals
- No manufacturer validated instructions
- Possible patient exposure risk
- Unknown affect with sterilization chemicals
- No manufacturer compatibility

1. Manufacturers' Instructions for Use (IFUs) are accessible and referred to by staff (for endoscopes, endoscope accessories, and re-processing equipment).				*Look for physical evidence ("show me").*
2. Policies related to endoscope reprocessing methods are accessible to staff.				*Look for physical evidence.*
3. Safety Data Sheets (SDS) for each chemical utilized in endoscope reprocessing are readily available to staff.				*Look for physical evidence.*
4. Staff have received initial training with verification of competencies for all scopes, accessories and associated equipment (e.g. AER) and have updated competencies (annually).				*Look for physical evidence.*
5. Logs (electronic or paper) are maintained with full traceability of the scope (e.g. serial #) to the patient, including who processed the scope.				*Look for physical evidence.*
II. ENDOSCOPE REPROCESSING ROOM REQUIREMENT *with*				*Summon Facilities for questions or problems* *#1 - #5 in this section.*
1. Endoscope reprocessing room is free of any dividing walls (e.g. curtain, temporary dividers are not allowable).				*Procedural barriers are in place to prevent cross contamination.*
2. Decontamination room air pressure is negative to surrounding spaces.				*Door to room must be kept closed to maintain negative pressure.*
3. Room air exhausts directly outside (air cannot be reused elsewhere in the building).				
4. Minimum # of Air Changes Per Hour: Air is changed a minimum of 10 times per hour and 2 of the 10 air changes are fresh, outside air.				*There are no requirements for relative humidity or temperature.* *Look for physical evidence.*
5. Water quality is tested annually.				

Competency Completion & Verification

“Really, I am competent!”



...EPROCESSING TRACER TO...

Date: _____

...served and/or Interviewed): _____

Department: _____

Performance Criteria	Yes	No	N/A	Comments
...NERAL DOCUMENTATION REQUIREMENTS				
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Water quality is tested annually.				
Spill neutralizer is readily available as needed per high ...vel disinfectant manufacturers.				*Look for physical evidence.*
...doscope reprocessing room contains the following:				
• Sinks to manually clean flexible endoscopes				
• Separate hand-washing sink				
• Eyewash station (clean sink, may be hand-...ashing sink)				
...e: High-level Disinfectant:				*Ask the question: How do y... chemicals?*
...ctivates and mixes high-level ...d following manufacturers ...beginning of the day or ...e. Transfers high-level				

- Becoming increasingly difficult to complete
- Must include return demonstrations
- Cleaning “type” and model specific
- Who signed your competency?

Guidelines, Standards & Recommendations – Who Do We Follow?

The Joint Commission

SGNA Society of Gastroenterology Nurses and Associates, Inc.

AAMI Advancing Safety in Healthcare Technology

AORN

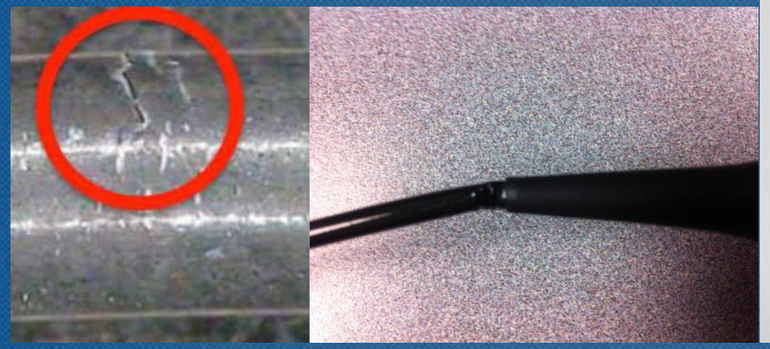
- Document annual staff review of IFU's
- Document annual staff review of applicable organizational guidance/standards

Technician Retention

- Technician compensation issue
- Proficiency takes experience, knowledge & dedicated responsibility
- Perpetual state of training & competency completion
- Higher risk due to errors
- Facility support
- Education & societal organizational involvement

PM is Not Just The Second Half of The Day:

- Formal PM plans are rare
- Requirements are not clear
- Annual PM inspection
- Maintain documentation

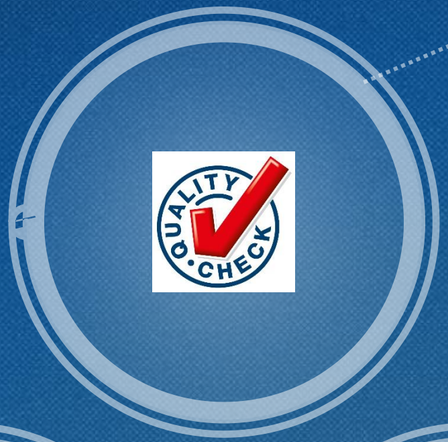


All Plans Should Reflect…

Inspection Documentation for:

Scheduled

Preventative Maintenance

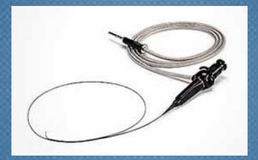


New Equipment

Receiving Inspection

Return

Repair Inspection



AAMI EQ 56 & 89

Preventative Maintenance

How to build a formal PM program is covered by AAMI EQ 56:2013

How to apply different maintenance strategies is covered in AAMI EQ 89:2015

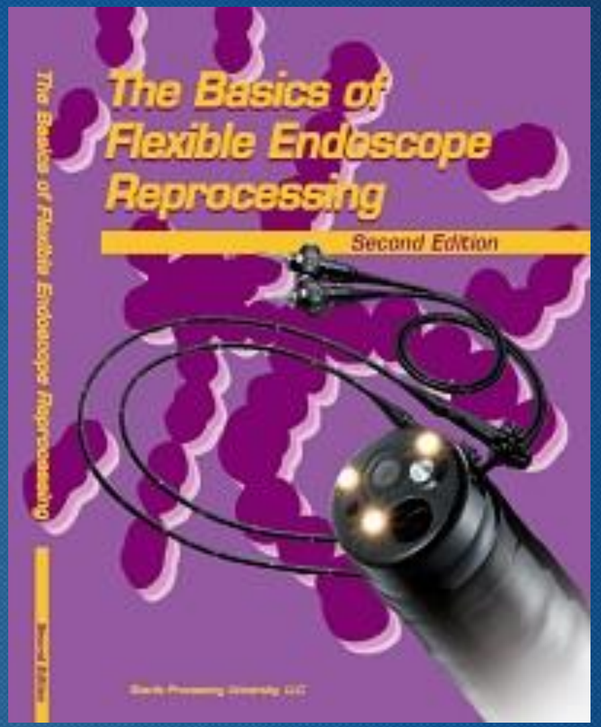
Reactive **Preventative** **Predictive**

New Challenges in 2020

Flexible Endoscope Reprocessing Certification

IAHCSMM
Instrumental to Patient Care®

CBSPD



New AAMI ST 91 Standard

Certification for all flexible endoscope reprocessing agents

IAHCSMM
Instrumental to Patient Care®

There are a couple sources for achieving certification:

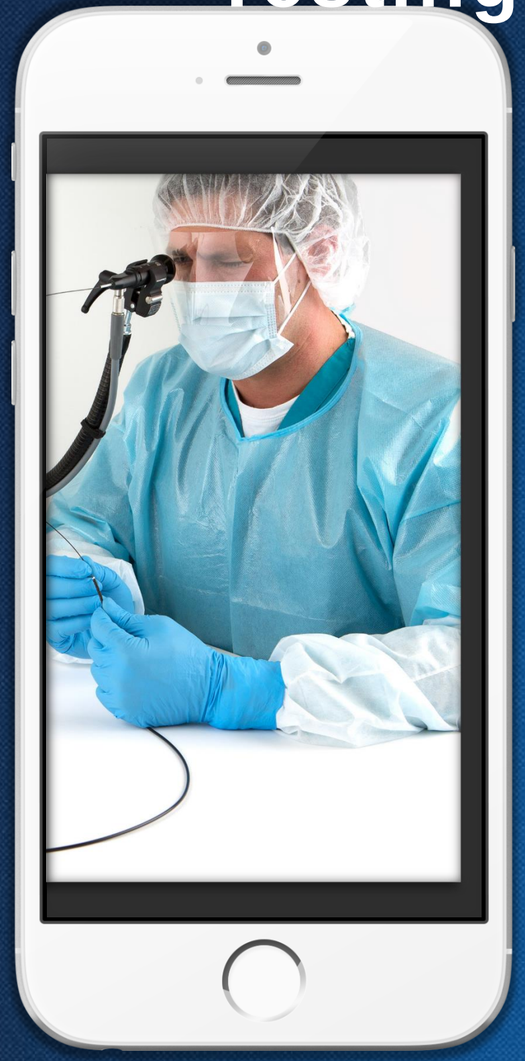
CBSPD

CER Certified Endoscope Reprocessor - IAHCSMM

C.F.E.R. Certified Flexible Endoscope Reprocessor - CBSPD

- Purchase of a manual is required and the workbook (optional)
- Hands-on experience for pre-approval prior to test
- Comparable certifications
- Membership often included at no charge for 1 year

Stronger Recommendations for Cleaning Verification Testing & Enhanced Lumen Inspection



Cleaning verification

- ATP
- Indicator test for protein, hemoglobin, or carbohydrates.

Borescope lumen inspection

- Various diameters and lengths
- Video or fiber optic versions

Esophageal Dilators are The New Scope:

- Unique identifiers
- Documentation for reprocessing traceability
- Lumen drying
- Storage requirements

Flexible Endoscopes & Sterilization: Where are we Now?

Duodenoscope Contamination

Duodenoscopes remain contaminated even under updated process instructions!

- 3.6% positive for low to moderate concern organisms
- 5.4% positive for high concern organisms such as E. coli and Pseudomonas aeruginosa [2]

Considerations on the Horizon

Disposable Component or Disposable Endoscope?

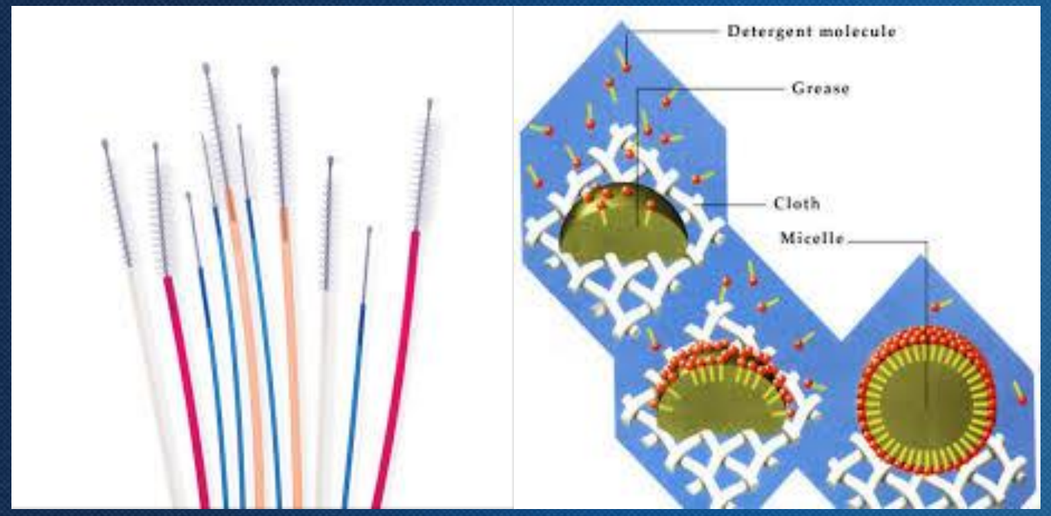
How ERCP Disposable would you go?

- Completely disposable sterile duodenoscope
- Disposable sterile end (including the elevator mechanism)
- Disposable distal end cover (not including elevator mechanism)
- Disposable end cap that works with existing reusable endoscopes

Emerging Disposable Devices

1. Current inventory
2. Risk reduction
3. New capital equipment needs
4. Overall cost savings
5. Satisfaction, case completion, and detection rates
6. Reimbursement
7. Loss of technological features
8. Image and picture quality
9. Turnaround case load
10. Impact on the staff
11. Environmental impact and cost of disposal

Cleaning Product Standardization



ANSI/AAMI

Compliance with FDA, AAMI and ISO standards

Resources & References:

Society of Gastroenterology Nurses and Associates, Inc. (SGNA). Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2016)pdf iconexternal icon. Published 1996. Revised 2000, 2005, 2007, 2008, 2011, 2012, 2015, and 2016.

Society of Gastroenterology Nurses and Associates, Inc. (SGNA). Standard of Infection Prevention in the Gastroenterology Setting (2015)pdf iconexternal icon. Published 2015.

Essential Elements of a Reprocessing Program for Flexible Endoscopes–The Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC). 2016. Available at: https://www.cdc.gov/hicpac/pdf/flexible-

“Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff.,” U.S. Department of Health and Human Services - Food and Drug Administration, March 17, 2015.

ANSI/AAMI ST91:2015 Flexible and Semi-rigid Endoscope Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.

Rutala WA, Weber DJ, and Healthcare Control Practices Advisory Committee. “Guideline for Disinfection and Sterilization in Healthcare Facilities,” 2008.

Olympus, Fujinon/Fujifilm, and Pentax manufacturer IFU for 180/190, 530/600/700, and K/I series respectively.

1.) https://www.jointcommission.org/on_infection_prevention_control/high_level_disinfection_and_sterilization_scoring_re-evaluated/

2.,3.) FDA Safety Communication: The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication

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Thank you…

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