The State of Endoscope Reprocessing – An American Perspective

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Objectives

- Discuss the current applicable standards and guidelines for reprocessing endoscopes in the US
- Outline recent FDA recommendations pertaining to duodenoscopes as part of a safety alert
- Discuss the future state of endoscope reprocessing and where standards are expected to go

The ECRI 2019 List

- Cleaning and disinfecting flexible endoscopes between uses is known to be a challenging process.
- Failure to precisely follow a robust reprocessing protocol can lead to debilitating or even fatal infections.

The List for 2019

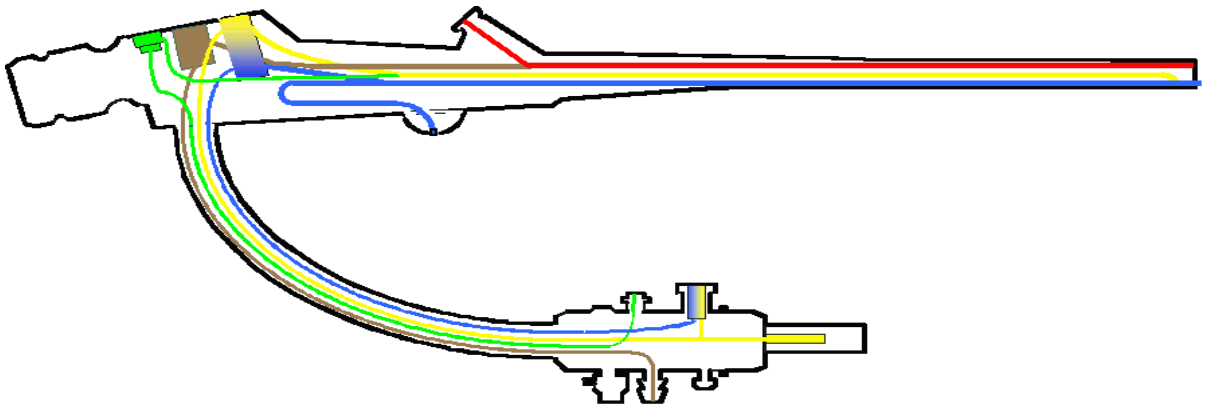
1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death
5. Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
6. Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors
7. Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms
8. Injury Risk from Overhead Patient Lift Systems
9. Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires
10. Flawed Battery Charging Systems and Practices Can Affect Device Operation

ECRI Endoscope Recommendations 2019

- Improper handling and storage can recontaminate disinfected scopes.
  - Improper drying after HLD remaining bacteria can multiply.
  - To promote drying ECRI recommends purging endoscopes with clean air after reprocessing.
  - Handle reprocessed scopes with clean gloves.
  - Transport disinfected and dried scopes in a clean, enclosed, dedicated container and prevent from contacting potentially unclean surfaces.

Reference ECRI 2019: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_19.pdf

What is the issue?



- Devices have:
  - Multiple Channels
  - Dead ends/right hand turns
  - Channels that aren’t brushed
  - High levels of soil and bacteria
  - Difficult cleaning instructions
  - Staff that is not highly educated or paid well
- Leads to poorly cleaned devices and failed disinfection cycles.
- Can result in infections

Transmission of Mobile Colistin Resistance (*mcr*-1) by Duodenoscope

- The first healthcare-associated transmission of mcr-1 in the United States was associated with shared exposure to a duodenoscope, despite implementation of updated reprocessing instructions and supplemental measures; this represents the first documented duodenoscope-linked transmission since publication of updated reprocessing guidelines.
- Evaluation of the duodenoscope identified an area at the distal tip where adhesive had peeled off; after disassembly, foreign material was detected on the interior of the distal case and at the distal tip of the duodenoscope body.
  - VISUAL INSPECTION!!

APPLICABLE US STANDARDS AND GUIDELINES

2019

Regulations/Standards/Guidelines

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory
- Standards
  - Requirements and specifications to ensure consistency and fit for purpose
  - Voluntary, but can become mandatory
- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation

What are these standards and guidelines based on?

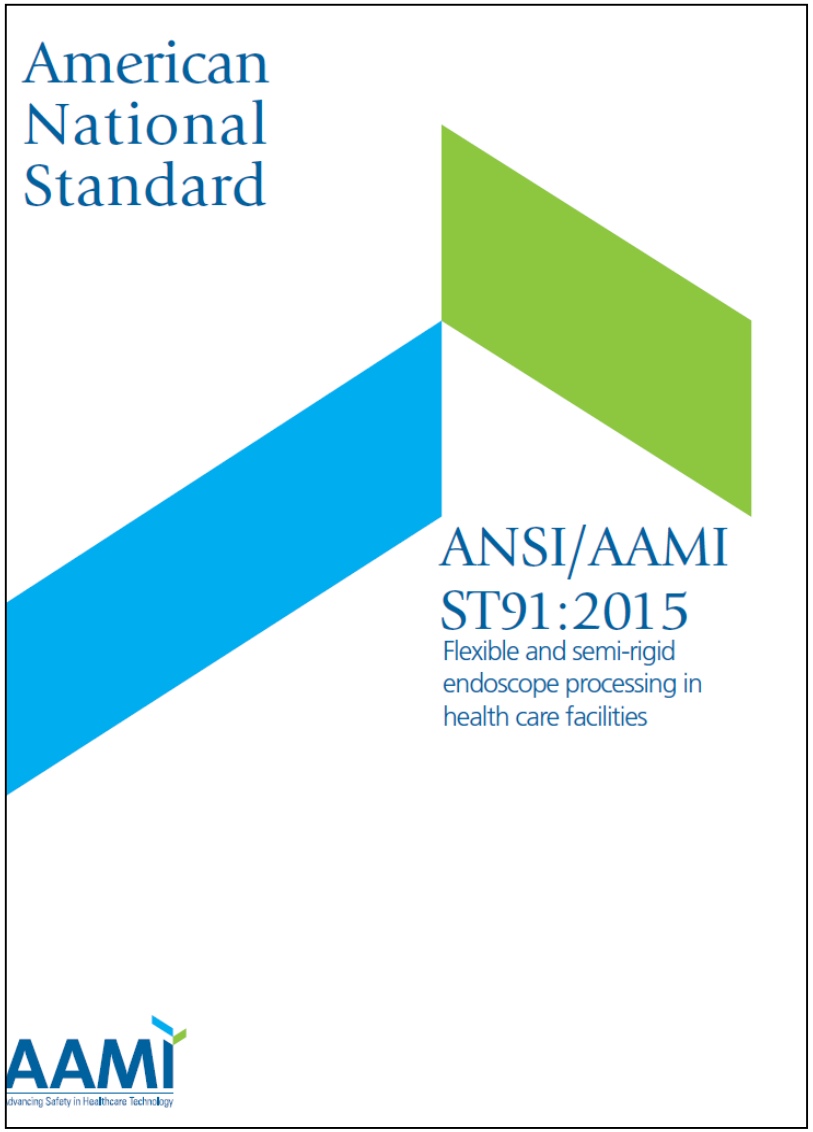
- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of your process

- Clinically relevant & evidence-based practices
- Peer-reviewed literature
- Other articles
- Manufactures research and guidance
- Research and science
- Some practices do not have the evidence to support the practice
- Dynamic process

What do the words mean within an AAMI Document?

- **MUST=** only describes an “unavoidable” situations, including those mandated by government regulation.
- **Shall=** requirements strictly to be followed to conform to the recommended practice.
- **Should=** indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that a certain possibility or course of action should be avoided but is not prohibited.
- **May=** indicates that a course of action is permissible within the limits of the recommended practice.
- **Can=** a statement of possibility and capability.

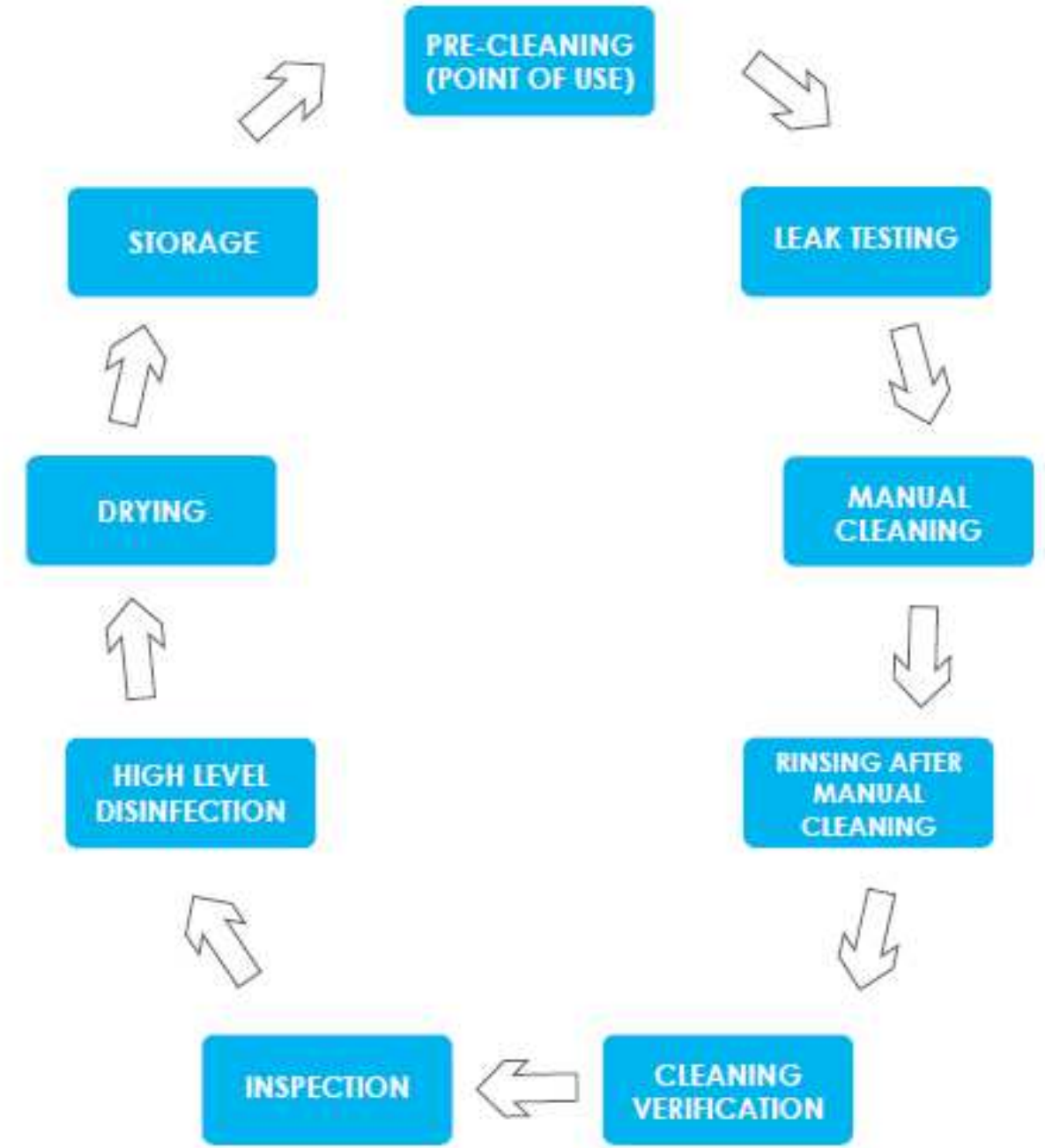
What is ANSI/AAMI ST 91?



- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for scope reprocessing in ANY setting
- Excludes TEE/ultrasound probes/dilators/manometry and rigid scopes
- Covers ALL steps of processing from precleaning through reuse

http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=2477

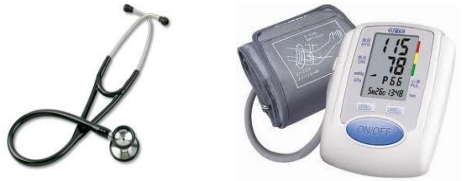
Reprocessing Cycle for Endoscopes - HLD



Highlights of AAMI ST 91

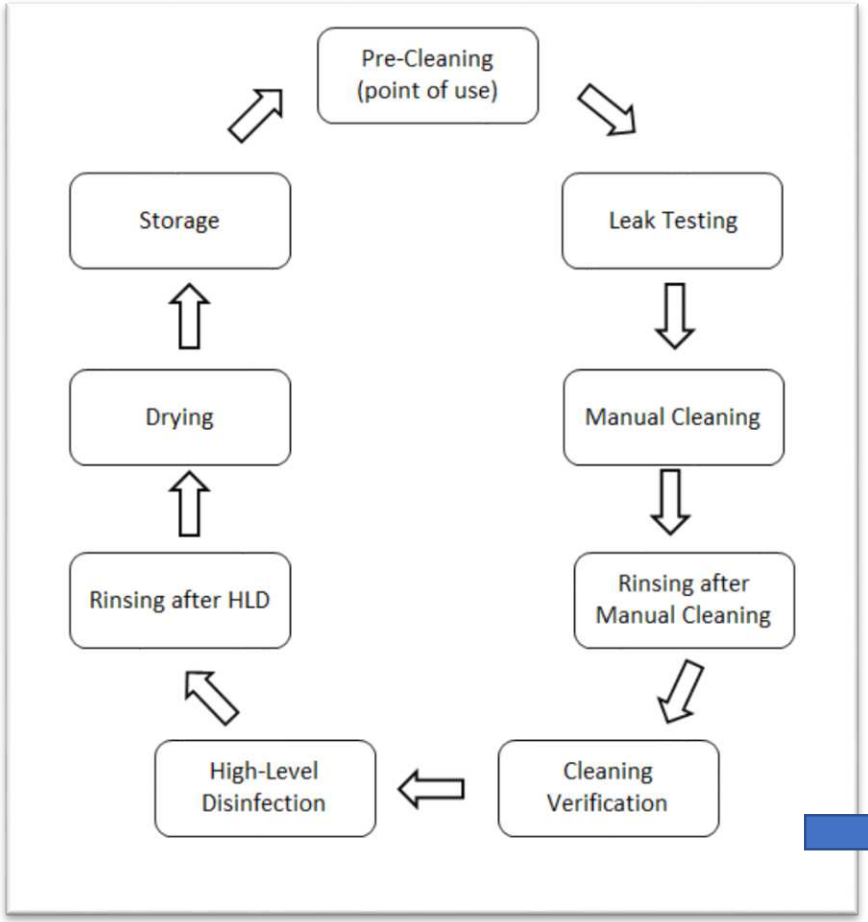
- Gives recommendations for:
  - Certifications for technicians performing reprocessing
  - Monitoring the manual cleaning process
  - Monitoring the automatic cleaning process
  - Monitor water quality
  - Monitor temperature
  - After cleaning, all detachable valves should be kept together with the same endoscope as a unique set
- Risk Assessment
- Proper documentation and quality assurance parameters

Spaulding Classification

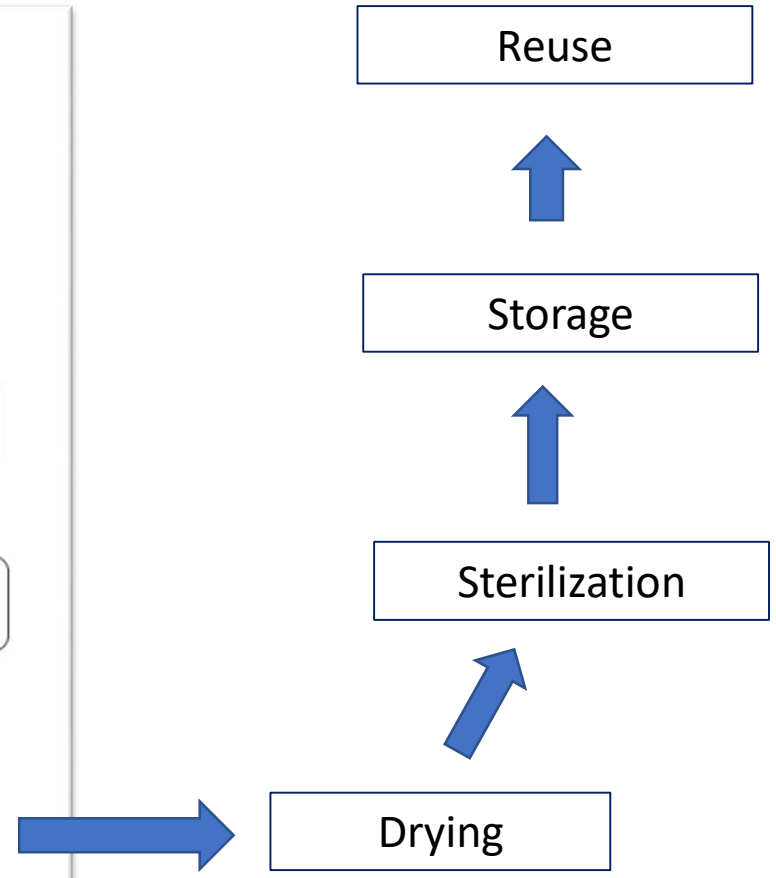
Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and **Sterilization** * If not possible, then High-Level Disinfection
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization

Endoscope Reprocessing Workflow

HLD



Sterilization



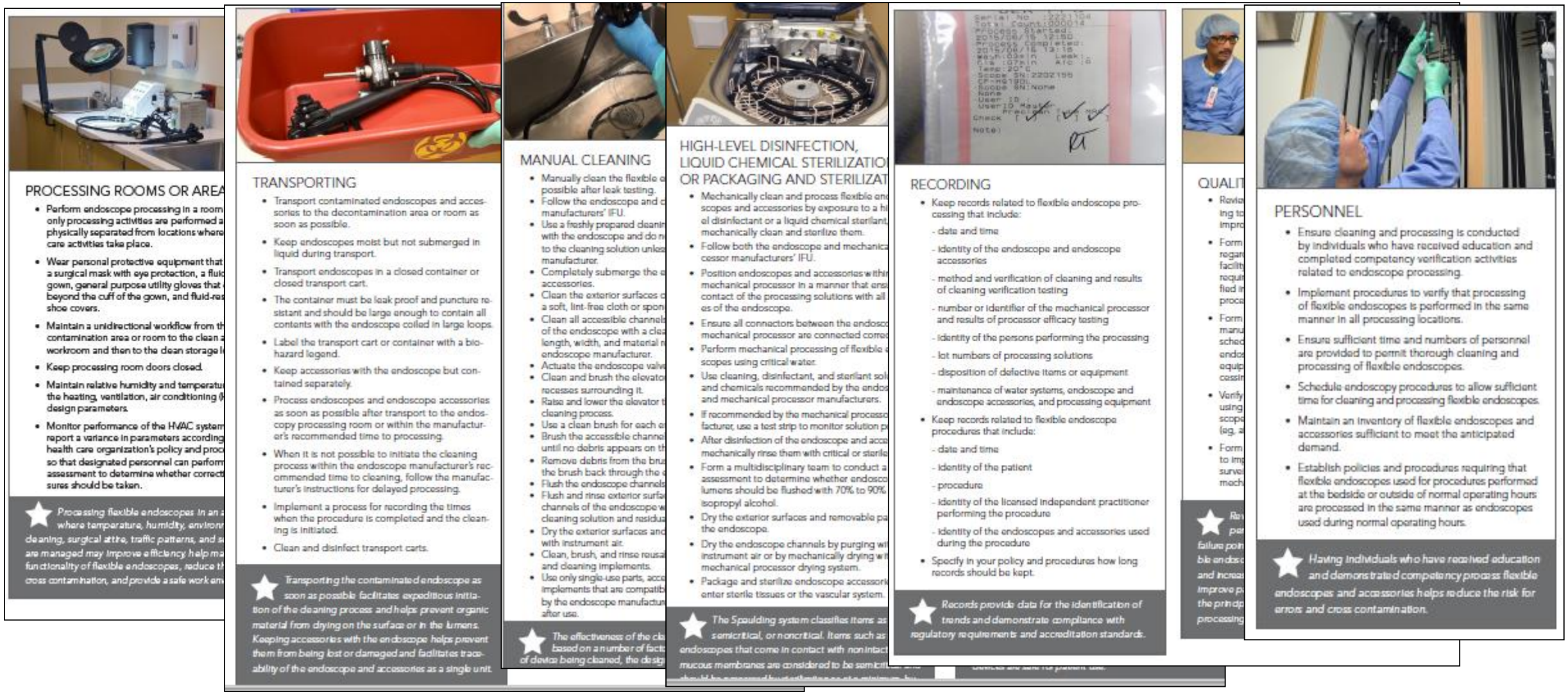
Applicable SGNA Guidelines

Infection Prevention

- **Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting (2018)**
- **Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes (2016)**
- **Guidelines for the Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting (2017)**
- **Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2018)**
- **Standards of Infection Prevention in the Gastroenterology Setting (2019)**

- https://guidelines.sgna.org/Standards-of-Infection-Prevention-in-Reprocessing-of-Flexible-Gastrointestinal-Endoscopes, accessed 7/3/2019.
- https://guidelines.sgna.org/Standard-of-Infection-Prevention-in-the-Gastroenterology-Setting, 7/3/2019.
- https://guidelines.sgna.org/Management-of-Endoscopic-Accessories-Valves-and-Water-and-Irrigation-Bottles-in-the-Gastroenterology-Setting, accessed 7/3/2019.
- https://guidelines.sgna.org/Guidelines-for-the-Use-of-High-Level-Disinfectants-Sterilants-for-Reprocessing-Flexible-Gastrointestinal-Endoscopes, accessed 7/3/19.

AORN Endoscope Guidelines



AORN. Guideline Essentials, Flexible Endoscopes at a Glance, 2019 – aorn.org

ST91 – next edition

- Hopefully Spring 2020
- Draft (CDV-1) went out for review and comment Sept. 2019
- Meeting Oct. 15-16 to resolve ~400 more comments
  - Some negative votes
  - Resolved all comments during that meeting
  - Made some substantive changes
  - Compiled into a new CDV-2
    - Committee and public review

TIR 99 – Reprocessing of Endoscopic Probes and Dilators

- TEE Probes, Vaginal Probes, Rectal Probes, and Dilators
- Potential to expand to other relevant accessories and devices such as manometry probes
- First draft circulated for review by committee
- Comments currently being reviewed
- Resolved comments will be incorporated into a new draft

- Hopefully 2020 or 2021

The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

- 8/29/19 – Recommending transition to newer designs of that aid in or eliminate reprocessing (e.g. disposable scopes, disposable tips)
- Ensure staff are meticulously following reprocessing **instructions.**
- Postmarket safety surveillance programs are finding a ~ 5% culture positive with high concern organisms after proper reprocessing
- Human factors study showing that user materials for Olympus duodenoscopes are not sufficient to consistently ensure user adherence in these core reprocessing area and therefore users are not following the IFU properly.
  - i.e. Steps are not being complete as written.

https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication

Other important FDA recommendations

- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Consider supplemental measures (sterilization or liquid chemical sterilant processing system) as compatible and consistent with the scope's labeling.
- Monitor your reprocessing procedures.
  - Examples of monitoring are sampling and culturing using the Duodenoscope Surveillance Sampling & Culturing
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.

ATP Confusion

Potential for Monitoring Reprocessing Effectiveness

- One potential method to monitor the effectiveness of duodenoscope reprocessing is the use of test strips that detect ATP, an indicator of the presence of live microbes.
- While some manufacturers of ATP test strips are promoting ATP test strips for assessing duodenoscope cleaning, as of August 29, 2019, we are not aware of any ATP test strips legally marketed for this use.
- The FDA premarket review is necessary to assess whether ATP test strips for this use are adequately validated and properly labeled.
  - FDA has contacted manufacturers of ATP test strips advising them of our requirements for manufacturing, testing and labeling for medical devices promoted for assessing duodenoscope cleaning.

FDA Duodenoscope Recommendations

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015

- Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.

- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- ~~Repeat High-Level Disinfection~~
  - This option is no longer mentioned in the new FDA safety alert

https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm457132.htm

Microbial Surveillance

- Options include:
  - Traditional culturing
  - Gram negative test kits
- **Not cleaning verification tests such as ATP or Protein**

- AAMI - No recommendation is made in the current version because of the timing of release.
  - Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing
- AORN: Base decision on a risk assessment
- SGNA: Surveillance cultures can be used as a method for assessing reprocessing quality and aid in identifying particular endoscope defects that hamper effective reprocessing

FDA Duodenoscope Culture Method

- Released 2-26-18
- Validated method
  - Scope manufactures, laboratories, & experts in the field
- Supersedes the CDC Interim Method
- Sampling and culturing
- Flush – brush – flush method (sterile water)
- Recommends a neutralizer broth (DE)
- Longer incubation time (72 hours)

https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf

The future

- FDA meeting on duodenoscopes - Nov. 6-7
- ASGE meeting – Dec. 2
- New ST91 - 2020

- Disposable scopes – already on the market
- Single use tips – already available
- Sheaths – not sure
- Automated cleaning machines

Thank you so much!

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