Are you Ready for the NEW AAMI ST91 for Endoscope Processing?

Mary Ann Drosnock

MS, FAPIC, CIC, CFER, RM (NRCM), AAMIF

Healthmark Industries

Director of Clinical Affairs

Co-Chair of AAMI ST91

APIC DFW

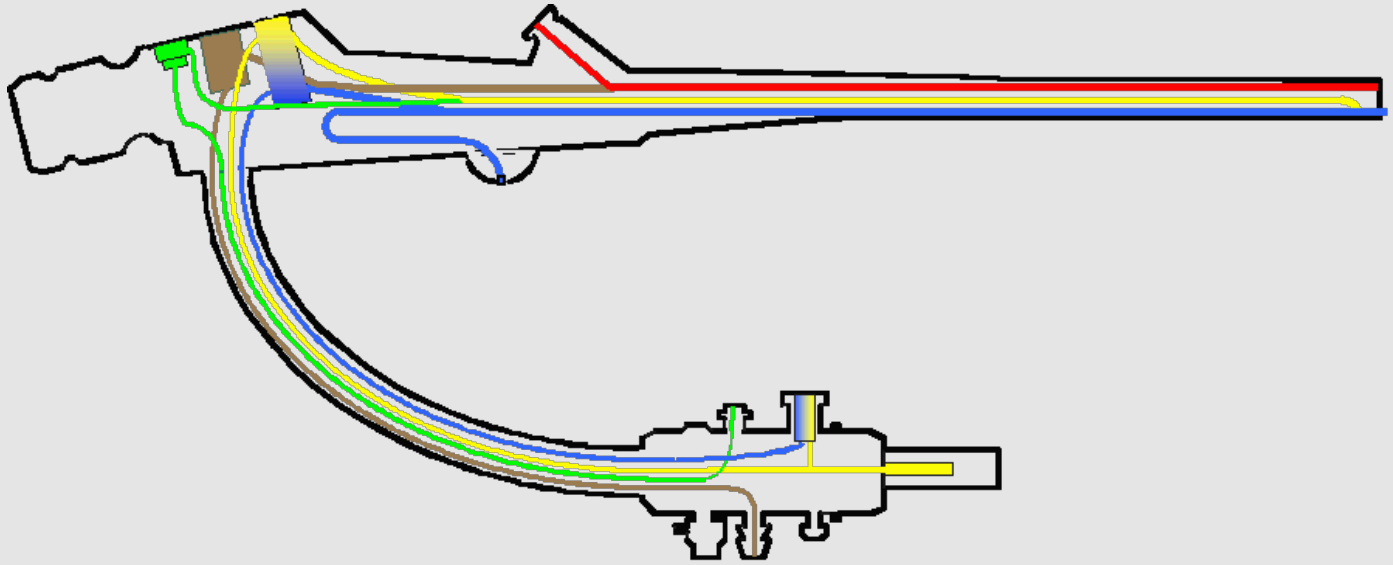
Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

Objectives

- Discuss the updated national standard, ANSI/AAMI ST91, highlighting key differences between the 2015 version and the latest update.
- Identify current best practices in the processing of flexible endoscopes as outlined in ST91 and other guidelines
- Outline how engineering quality assurance parameters into endoscope processing can help to reduce Hospital Acquired Infections (HAI) and Surgical Site Infections (SSI) and help to determine if an endoscope is patient ready

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
- Leads to poorly cleaned devices & failed disinfection cycles
- Can result in infections

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

OSHA Occupational Safety and Health Administration www.osha.gov

CDC SAFER • HEALTHIER • PEOPLE™

AAMI Advancing Safety in Medical Technology

ANSI

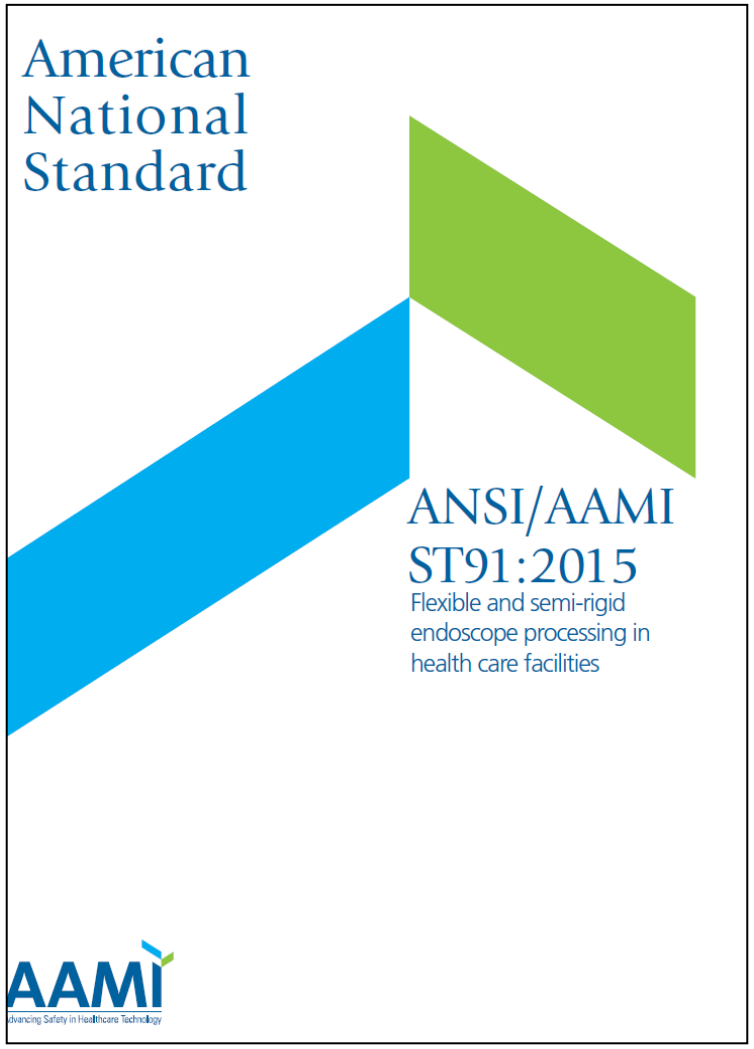
AORN

SGNA

Word Meaning Within AAMI Documents?

- **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.
- **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

ST91: 2021 – coming soon!

- Update on current stage in the process
- By October it should be finalized or waiting for ANSI final approval

New Guidance

Let’s jump in!

Design of Processing Area

Should be:

- Physically separated from patient care areas & procedure rooms
- Designated for processing only
- Designed for the unidirectional flow of devices from the receipt of used endoscopes to storage prior to next patient use
- Two separate rooms for processing endoscopes
  - Until such time that 2 separate processing rooms can be provided, strict unidirectional flow
  - If a single-room, minimum 4 feet of separation between decontam and clean work area with a wall or barrier extending 4 ft above sink rim
- Adequate space provided to allow for cleaning and rinsing
- Minimum 2 sinks for manual cleaning and rinsing

Point of Use Treatment

Formerly known as Precleaning

- Consistent terminology with ST79

Note the time of point of use treatment completed and convey that info to processing staff

- Needed to determine if delayed reprocessing is required

If there is a delay and/or failure to perform point of use treatment, the endoscope should be processed using delayed processing protocols described in the device manufacturer's IFU

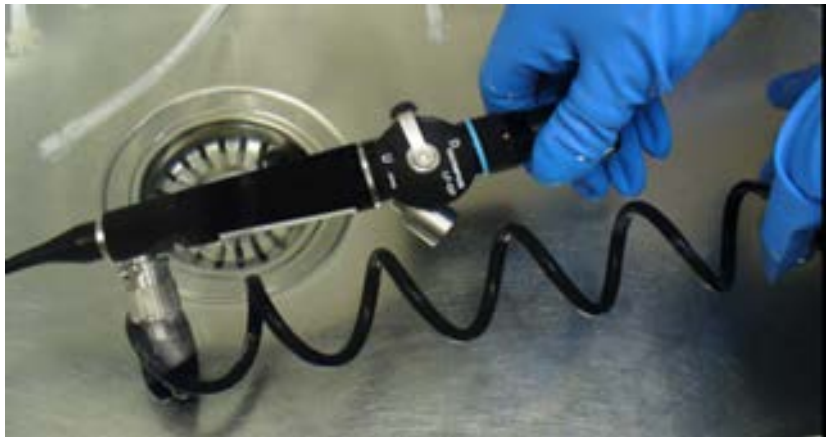
- Typically, 1 hour

Transport of Soiled Endoscopes

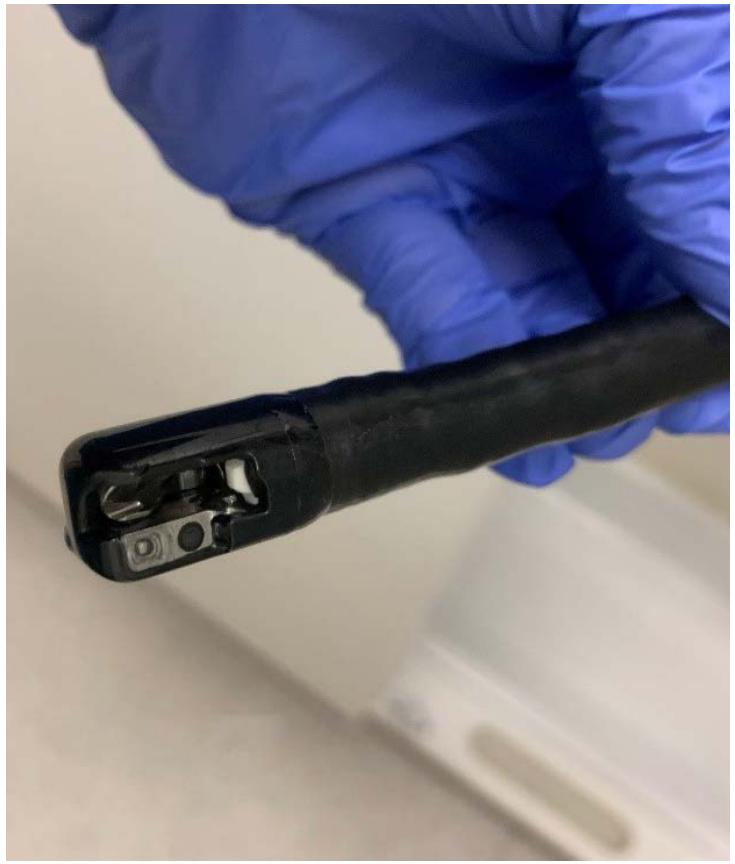
- Isolate & transport endoscope with its components in a closed container or closed transport cart
- The transport cart or container **must** be labeled with a visible fluorescent orange, orange-red, or red label containing a biohazard label & must meet OSHA requirements (29 CFR 1910.1030) for transporting hazardous items.
- The closed container or closed transport cart must be nonporous, leak-proof on its sides and bottom, puncture-resistant, and large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.
- Keep endoscope moist but not submerged for transport
    - Pretreatment solution, water-moistened towel, or humidity chamber bag

Leak Testing

- **Should** not use endoscopes that can not be leak tested
- Regularly calibrate automated leak testers to verify the correct pressure output
- Inspect manual and hand-held units for damage, leakage and correct pressure output
- Verify each type of tester each day that endoscopes are used
  - Document results
- Wet leak testing – minimum observation of 60 seconds (not 30)



Identifying High Risk Endoscopes



- Those associated with infectious outbreaks that are difficult to process and have increased risk
- Or those with complex design
- Duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes and as determined by the facility

Cleaning Verification Testing

- High risk scopes - **Shall** be monitored with cleaning verification after each cleaning.
- Scopes not high-risk: **Should** be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed).
    - See Annex F, for statistical frequency determination.
    - Consider other factors: endoscope type, technician competency, procedural characteristics (e.g., duration, complexity, and heavy soiling), or delayed reprocessing.

Visual Inspection

- Endoscopes **SHOULD** be inspected with each reprocessing cycle
- Lighted magnification **SHOULD** be used to inspect for debris and damage
- FDA recommend 5 -10x magnification for duodenoscopes

Borescope Inspection

- Internal Channels can be inspected with a borescope
- Can be used periodically at a frequency determined by the facility
- Make sure endoscope is dry prior to inspecting
- If used on a processed endoscope, process the endoscope again before clinical use
- If a scope repeated fails cleaning verification, may want to inspect with a borescope before sending for repair

Manual Disinfection

- Manual disinfection for processing is not recommended
  - If necessary, consult the endoscope manufacturer's written IFU for instructions and compatibility
  - When would you use it?

- Manual high-level disinfection and liquid chemical sterilization is not recommended due to variability and inconsistency in the personnel responsible for the process (see 8.2.4)

HLD or Sterilization

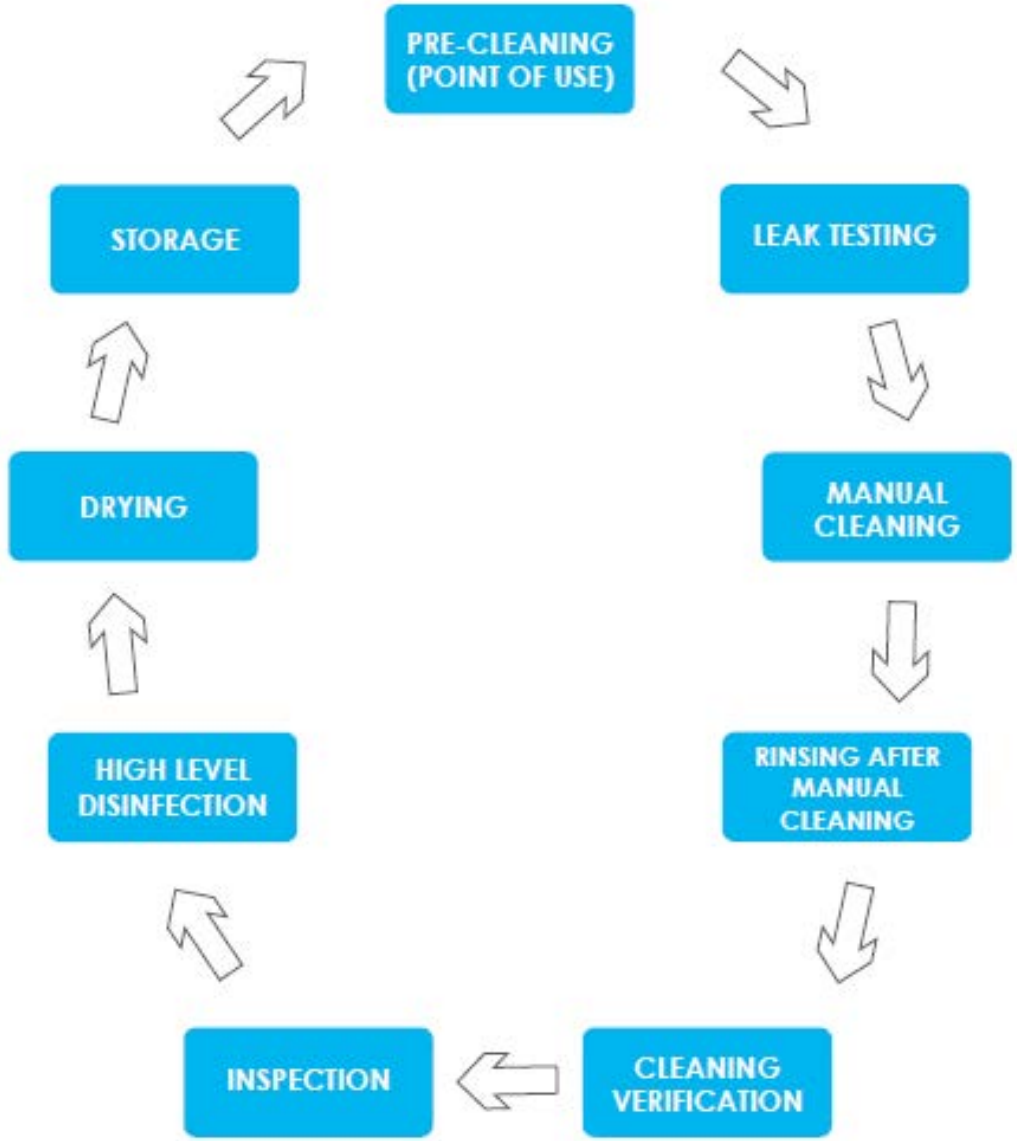
- Semi-critical devices contact mucous membranes or non-intact skin.
  - Thoroughly cleaned and then sterilized.
  - If sterilization is not possible, high-level disinfection is the minimum advised processing method
  - Workgroup did not require sterilization for all scopes

- It is advised that flexible and semi-rigid endoscopes used in semi-critical applications be **sterilized** prior to use
- Transition from HLD to sterilization as the standard of care may be accelerated by identifying and addressing key technical and compatibility obstacles and defining priorities and key steps
  - Contribution of reusable medical device manufacturer is essential. Partnerships between sterilizer and medical device manufacturers are encouraged

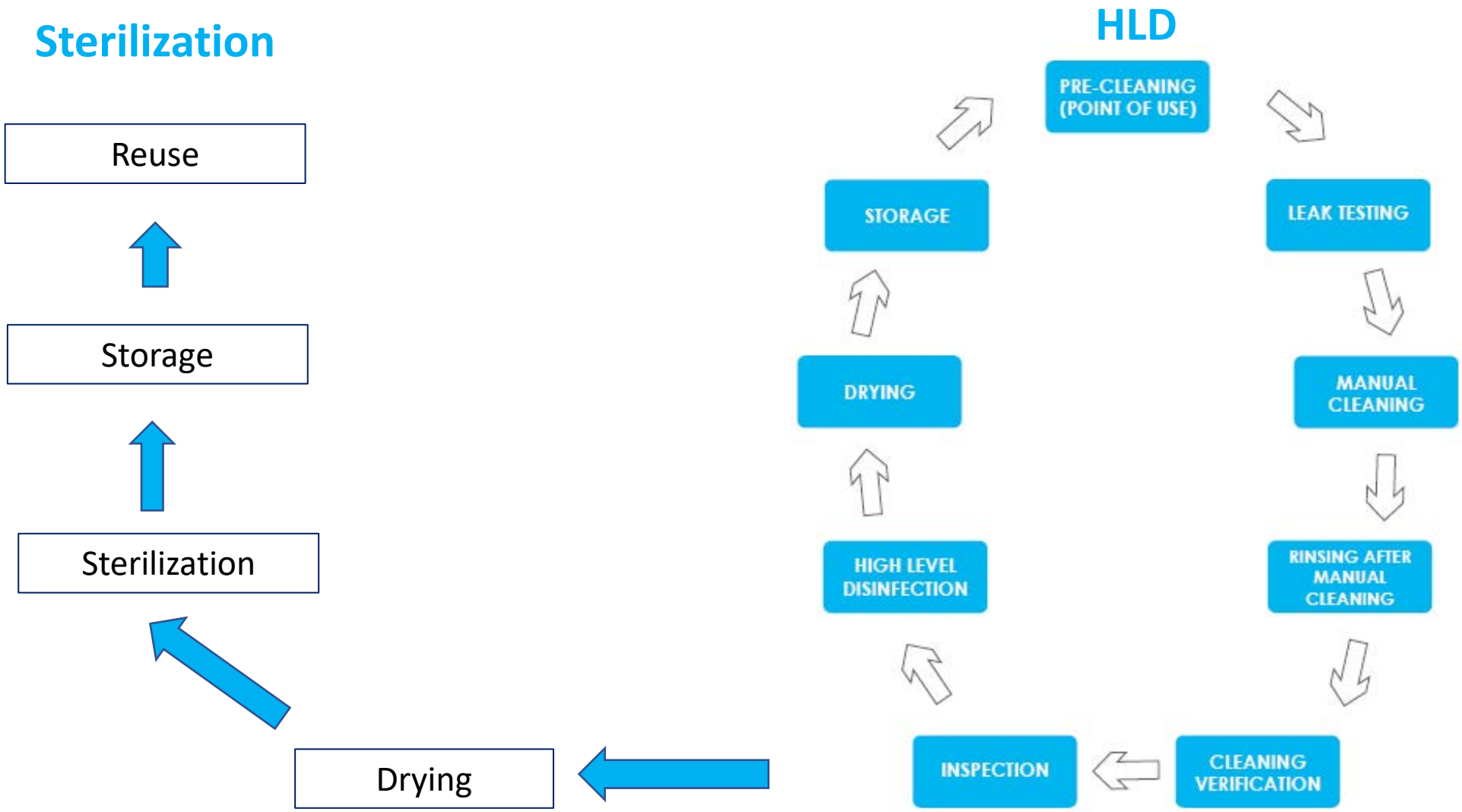
Spaulding Classification

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

Traditional Reprocessing Cycle for Endoscopes - HLD



Endoscope Sterilization Workflow



Drying

- Endoscope should be dried after cleaning & disinfection process.
  - a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air
  - Never store scopes wet
- Dry externally with a unused, clean or sterile non-linting cloth
- Complete active drying cycle even after a scope has come out of an AER.
  - AER’s have an air purge, not drying
- Create a multi-disciplinary team to evaluate alcohol flush

Storage

- Endoscope is dry prior to storage in a cabinet or place into a drying cabinet
- If manually drying, verify that the scope is dry.
  - Dryness can be checked with an indicator test
- Cabinet should have minimum HEPA filtered air
- Maximum storage time based on a risk-assessment
- Identify patient-ready scopes with a distinct visual cue
- Located in a secure location, such as clean workroom, not procedure room
- Visually inspect cabinet for cleanliness, clean at least weekly (per IFU)

Handling Processed Endoscopes

- Perform hand hygiene and don new clean non-latex gloves to handle processed endoscopes
- Identify the endoscopes as clean to transport to point of use
- Protect from contamination and damage by containerizing
  - Unless in a controlled, connected corridor
- Reprocess containers between uses per the IFU of the container
- Container for transport should be: clean, covered, solid protective containers (that are) nonporous, (and) leak-proof on sides and bottom

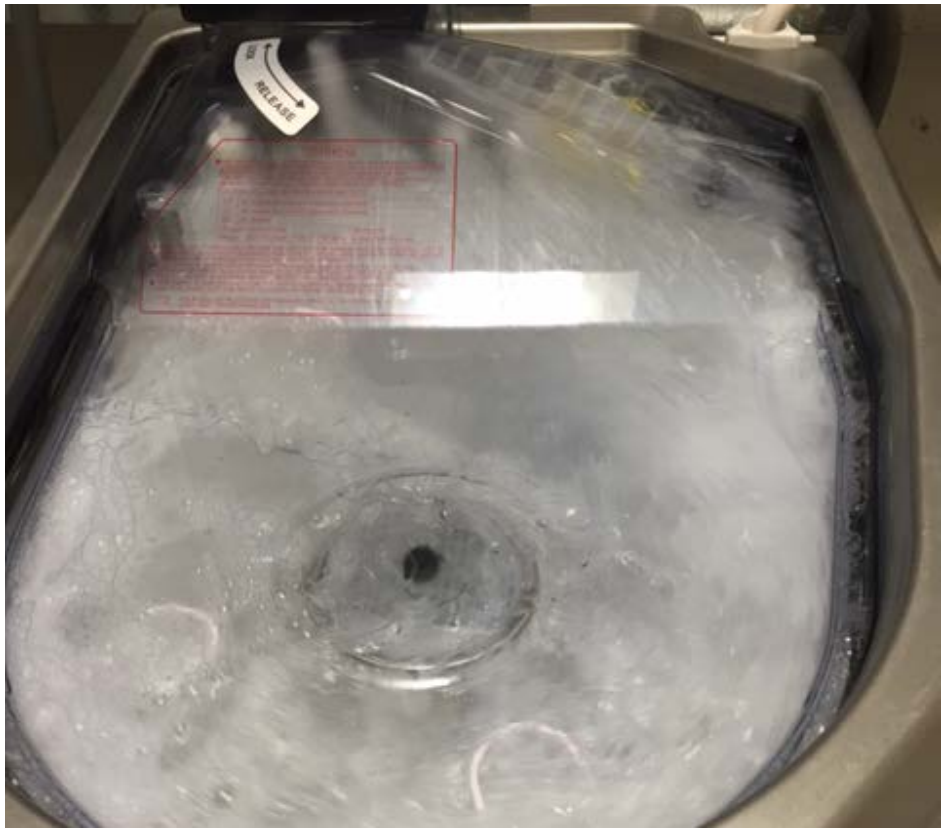
Personnel – Training and Certification

All personnel **SHALL** complete formal training and competency verification in all aspects of endoscope processing prior to 1st assignment.

All personnel performing processing of endoscopes **SHOULD** be certified in flexible endoscope processing within two years of employment and should maintain that certification throughout their employment.

Water Quality

- **Should** monitor and control the water supply quality to endoscope processing sinks and equipment.
- **Should** consider periodic microbial assessment of the AER to identify water contaminants or contaminated equipment which may contribute to recontamination of the device after high-level disinfection.
- Periodic microbial assessment of the water used for final rinse should be considered to identify any contaminants which can contribute to recontamination of the device after disinfection.



References and Citations

- Addition of references as support
- Adding FDA MAUDE database citations
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

Appendices

- Several new/updated appendices:
  - Keeping cool
  - Purchase considerations for AERs
  - Repairs
  - IFU conflict management
  - Visual inspection
  - Cleaning verification
  - Simethicone
  - Use of HLDs and sterilants
  - Storage risk assessment
  - Drying

TIR 99 – Reprocessing of Ultrasound Probes and Dilators

- TEE Probes, Vaginal Probes, Rectal Probes, and Dilators
- Update on status of document
- Expected in 2022

How Can I Get a Copy?

- Available for purchase
  - https://store.aami.org/s/store#/store/browse/cat/a0s2E000008YVpaQAG/tiles
- List price and member price
  - Your healthcare facility should be a member of AAMI
- Available electronically first, print later

References

AAMI ST91: 2021

AAMI TIR99

FDA MAUDE database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

And as noted on slides

Thank you!

Mary Ann Drosnock

Director of Clinical Affairs

Healthmark Industries

mdrosnock@hmark.com