ANSI/AAMI ST91:2021

Updates to Endoscope Reprocessing Guidelines

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1

Introduction

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Disclosures : none

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2

References

- ANSI/AAMI ST91 (2015). Flexible and semi-rigid endoscope processing in health care facilities
- ANSI/AAMI ST91 (2021). Flexible and semi-rigid endoscope processing in health care facilities
- Drosnock, M. A. (2022). Are you ready? An Updated AAMI ST91 for endoscope processing
- Drosnock, M. A. (2022). The New AAMI ST91: An Updated Standard for Flexible Endoscope Processing

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3

Objectives

- Outline changes between the ANSI/AAMI ST91:2015 Guideline and the ANSI/AAMI ST91:2021 Guideline.
- Identify types of high-risk endoscopes and their requirements for reprocessing.
- Discuss the concepts of cleaning verification, active drying, and microbial surveillance as they apply to endoscope reprocessing.
- Discuss the importance of Quality Assurance steps in the reprocessing cycle.
- Apply concepts from the ANSI/AAMI ST91:2021 Guideline to develop best practices, policies, and procedures for reprocessing flexible endoscopes.

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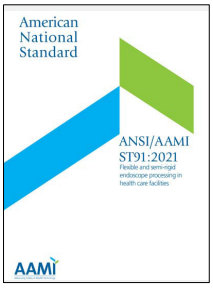
4



About ANSI/AAMI ST91:2021

- Approval
- Normative sections vs Informative appendices
- Evidence based data
- New sections

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5

Terminology

- **MUST** - an unavoidable action or procedure that a facility is required to do
- **SHALL** - the standard is based on evidence or strong consensus; is to be strictly followed to be considered as conforming to best practices
- **SHOULD** - the standard is a **recommendation** but not required
- **SHOULD NOT** - a certain action should be avoided but is not prohibited
- **MAY** - an action is permissible and is within recommended practice
- **CAN** or **MIGHT** - an action is possible for a facility to do

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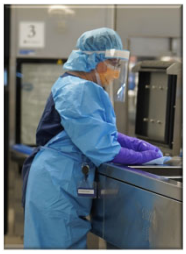
6

ANSI/AAMI ST91:2021, Section 6.6.2

Personal Protective Equipment (PPE)

- Proper selection of PPE for the situation
- Proper use and disposal of PPE
- **Emphasis on changing PPE**
  - After manual cleaning, before performing cleaning verification and inspection
  - After placing in and before removing from an automated reprocessor (AER)
  - When transporting endoscopes from processing to storage
  - When removing endoscope from storage cabinet



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7

ANSI/AAMI ST91:2021, Sections 6.3.1-6.3.6

Certification, Training, & Competency Validation

Certification

- Obtain within 2 years of employment
- **Should** be maintained

Education, training, and competency validation **shall** occur:

- Prior to staff working independently & ongoing annually
- At designated intervals determined by the facility
- When new endoscopes, processes, or products are added
- On all reprocessing procedures for all devices in facility inventory
- Maintain documentation for all staff

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ANSI/AAMI ST91:2021, Section 4

Department Design and Layout

Shoulds:

- Processing area physically separated from procedural/patient care areas
- Strict unidirectional flow: Dirty → Clean
- Two-room design
- Three sinks ideal, minimum two
  - Leak testing and manual cleaning
  - Rinsing only
- Designated drying area
- Physically separated storage area

9

ANSI/AAMI ST91:2021 Section 3.31

High-Risk Endoscopes

Pose a greater risk of cross contamination and patient infection

- Six specific types:
  - Bronchoscopes
  - Cystoscopes
  - Duodenoscopes
  - Ureteroscopes
  - Endobronchial ultrasounds (EBUS)
  - Linear ultrasounds (EUS)
- Others as determined by the facility based on
  - Patient population
  - The type and characteristics of procedure

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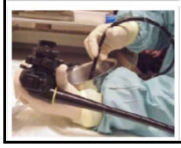
10

ANSI/AAMI ST91:2021 Sections 3.56 & 6.3.4.1

Point of Use Treatment



Point-of-Use (POU) Treatment

- Should occur immediately after patient use regardless of location

Hand-off process from POU to Decon shall include

- Patient identifier, date & time POU was completed
- Facility determined process based on risk assessment
- Consistent communication to determine if delayed processing is needed

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ANSI/AAMI ST91:2021 Section 7.3

Transport of Contaminated Endoscopes

- Endoscopes **should** be kept moist
- Endoscopes **should** be isolated and transported in a closed container or approved transport bag that is
  - Nonporous
  - Leak-proof
  - Puncture resistant
  - Labeled as biohazard
- Use of hand-off process

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12

ANSI/AAMI ST91:2021 Section 7.1, 7.5.1 & Annex F

Delayed Reprocessing

- Manual cleaning **should** begin as soon as possible
- Use Delayed Reprocessing Protocol
  - Delays in initiating manual cleaning
  - Heavily soiled endoscopes
- Follow instructions for use (IFU) *or*
- Initiate within one hour of POU Treatment or as determined by the facility through a risk-based assessment

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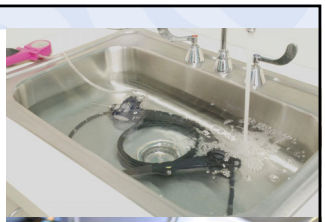
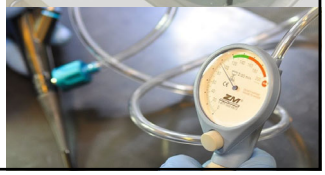
ANSI/AAMI ST91:2021 Section 7.4

Leak Testing

- Remove endoscopes from use for repeated failures
- Follow manufacturer IFU for leak tester and endoscope
- Wet leak testing observation increased to 60 seconds
- Validate leak tester pressure output each day used & maintain documentation
- Document outcome of all leak tests
- Policy and procedure for when a leak is found

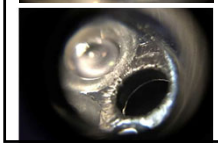




14

ANSI/AAMI ST91:2021 Sections 7.8, 13.5, Annex E

Enhanced Visual Inspection



- Endoscopes **should** be
  - Visually inspected at every touch point using lighted magnification
  - Completely dry before inspection
- Internal channels **can** be inspected with a borescope
- Follow endoscope IFU for what parts to inspect
- Conduct a facility-based risk assessment to determine process and frequency

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15

ANSI/AAMI ST91:2021 Sections 7.1, 7.6, 4.3.2, 6.6.4.2

Manual Cleaning

- Reinforces use of hand-off process and delayed reprocessing protocol.
- Manual Cleaning includes:
  - Rinsing with utility water
  - Drying the exterior; air purging internal channels according to IFU
  - Changing PPE prior to inspection
- Automated Endoscope Reprocessor (AER) use as a supplement to manual cleaning

16

ANSI/AAMI ST91:2021 Section 7.8, Annex F

Cleaning Verification

Evaluation for successful cleaning and removal of residual contaminants:

- **Should** include visualization and cleaning verification testing; **Can** include borescopic inspection
- High-risk endoscopes **shall** have a cleaning verification test **after each use**.
- Non-high-risk endoscopes when new and at facility-established intervals
  - **Should** be a statistically significant frequency

17

ANSI/AAMI ST91:2021 Section 8.1, Annex I

Sterilization of Endoscopes

- Spaulding Classification
  - Endoscopes that contact sterile tissue or vascular space **shall** be sterilized
  - Sterilization for **Semi-Critical** devices used in **a critical capacity**
- Risk assessment to determine if sterilization is indicated
  - Consider current processes, types of procedures being performed, and patient population

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18

ANSI/AAMI ST91:2021 Section 8.2

Manual Disinfection/Sterilization

Manual high-level disinfection and sterilization processes are not recommended

- Only in an emergency or lack of resources for automated processes
- Follow IFU carefully to standardize process
- Support with policy and procedure

Endoscopes that sit in an AER more than 1 hour **should** be reprocessed before patient use.

PPE **should** be changed between decontamination and removing from an AER.

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19

ANSI/AAMI ST91:2021 Section 8.2.5, Annex K

Endoscope Drying

- **Endoscopes should be completely dry before storage or patient use**
- Active drying process:
  - Continuous flow of pressure regulated instrument air or HEPA filtered air for a **minimum** of 10 minutes ***or***
  - Immediately place in active drying cabinet
- Follow endoscope IFU for maximum pressure (PSI)
- AER air purge/extended dry cycle is not considered active drying

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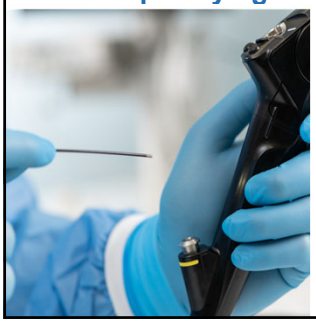
20

ANSI/AAMI ST91:2021 Section 8.2.5, Annex K

Endoscope Drying



- Separate cabinets and drying nozzles for clean vs. disinfected scopes
- Alcohol flush **can** be used – consider facility risk-based assessment to determine if necessary
- **Validation of drying:**
  - Facility risk assessment to determine processes/policy/procedure
  - Borescopic examination
  - Drying indicators
  - Extend drying time as needed

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21

ANSI/AAMI ST91:2021 Section 11

Storage Considerations

- Store vertically or horizontally
- Active drying and conventional cabinets are acceptable
- **Never** store endoscopes wet
- Valves and accessories **should** be stored as a unique set with the endoscope
- Identify patient-ready scopes with a **distinct visual cue on the endoscope**
- Hand hygiene and clean PPE when handling disinfected endoscopes in storage

22

ANSI/AAMI ST91:2021 Section 11

Storage Considerations

Maximum storage time (hang time) based on a facility risk-assessment

Storage Cabinets:

- Place in a secure, clean area separate from procedural rooms
- **Should** remain closed
- **Shall** be visually inspected for cleanliness when placing endoscopes in or taking out of the cabinet
- **Should** be cleaned according to manufacturer IFU, at minimum weekly, and when visibly soiled

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23

ANSI/AAMI ST91:2021 Section 13

Quality Monitoring

Quality monitoring plan in place that includes:

- Adherence to manufacturer IFUs and facility policies/procedures
- Monitoring and verification of personnel performance and work practices
- Cleaning and drying verification and microbial surveillance

Microbial surveillance:

- **Should** be incorporated
- Includes traditional culturing or Gram-negative test kits
- Is NOT the same as cleaning verification tests
- **Should** always be done for breakouts
- Facility based risk assessment to determine how to best implement

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ANSI/AAMI ST91:2021 Section 14

Device Repair and Preventive Maintenance

- Should have a Preventative Maintenance (PM) plan in policy/procedure
- Maintain documentation of service/maintenance records; review and use to make changes
- All reprocessing staff **should** be aware of PM policy
- Damaged endoscopes **shall** be clearly identified with the type and location of damage, and other information as directed by facility policy
- Communication methods for handing-off damaged endoscopes **shall** be detailed in a facility policy/procedure

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25

ANSI/AAMI ST91:2021 Section 14

Device Repair and Preventive Maintenance

- Continued failure of cleaning verification tests could indicate internal damage – remove device from service
- **Must** be fully reprocessed prior to transport out of the facility
- If device is considered contaminated, **must** be clearly identified and shipped according to the endoscope IFU and all relevant regulations
- Institute a documentation trail for damaged endoscopes, both out of and back into the facility
- Endoscopes returned from repair **shall** be completely reprocessed prior to use

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26

27