ASP SUMMIT
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Shine on Flexible Endoscope Reprocessing

2025 Webinar 01 | Series

What's New on Flexible Endoscopes Reprocessing Guidelines?

ASP Advanced Sterilization Products

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Intro

Flexible endoscopes remain among the most challenging reusable medical devices to clean, disinfect, and sterilize. This webinar will explore the most recent updates in international and national guidelines, highlighting critical changes aimed at improving patient safety and infection prevention. Participants will gain practical insights into the rationale behind updated protocols, including enhanced drying procedures, storage conditions, microbiological surveillance, and staff competency. The session is designed for CSSD professionals, endoscopy nurses, infection preventionists, and healthcare managers involved in endoscope handling and reprocessing.

Cleaning isn't just the first step, it's the most critical. If an item isn't cleaned properly, no machine in the world can make it safe. Biofilm does not forgive shortcuts, and neither should we.

Topic • 01

Enhanced Cleaning and Pre-Cleaning Protocols

This chapter will explore the critical importance of enhanced cleaning and pre-cleaning protocols in ensuring the safe reprocessing of reusable medical devices. The objective is to gain a clear understanding of how thorough soil removal and appropriate initial decontamination are foundational steps in preventing healthcare-associated infections and maintaining instrument integrity.[1-5]

Enhanced cleaning is not optional. It is fundamental to infection control. Preventing biofilm formation and reducing bioburden directly influence the effectiveness of high-level disinfection and sterilization.

The presentation will cover:

- **Biofilm formation and how prompt and proper pre-cleaning disrupts microbial colonisation.[7-9]**
- **Best practices in point-of-use treatment, including moisture retention and transportation methods.[1-5]**
- **Key elements of manual and mechanical cleaning processes, including detergent selection, water quality, and equipment validation.[7-9]**
- **Industry and national standards and guidelines that inform compliance and continuous improvement in the cleaning phase of the sterilization cycle.[7-9]**

This section will provide actionable strategies to implement evidence-based protocols that support quality assurance and patient safety.

The Role of Cleaning in Infection Prevention

"If it's not clean, high-level disinfection and/or Sterilization cannot be reached."

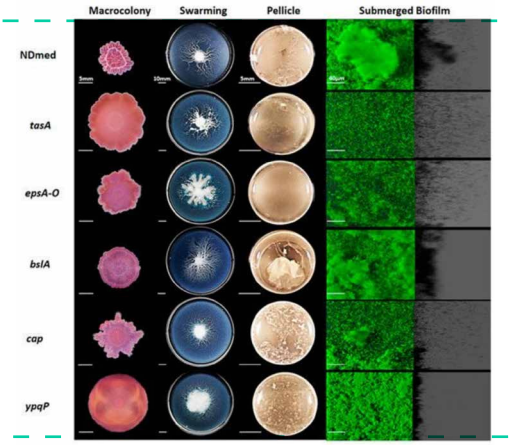


Image source: Multidisciplinary Digital Publishing Institute- https://www.google.com.au/imgres?q=Endoscope%20Biofilm&imgurl=https%3A%2F%2Fwww.mdpi.com%2Fmicroorganisms%2Fmicroorganisms-09-00633%2Farticle_deploy%2Fhtml%2Fimages%2Fmicroorganisms-09-00633-g002-550.jpg&imgrefurl=https%3A%2F%2Fwww.mdpi.com%2F2076-2607%2F9%2F3%2F633&docid=cG42JKKCHa34ZM&tbnid=LTHnV_4iuSCMZM&vet=12ahUKEwjj_dbZvqKNAxXTrlYBHYhNCUwQM3oECCEQAA..i&w=550&h=514&hcb=2&ved=2ahUKEwjj_dbZvqKNAxXTrlYBHYhNCUwQM3oECCEQAA

Topic • 02

Drying and Storage Requirements

Effective drying and appropriate storage are critical yet often underestimated stages in the Endoscope reprocessing cycle. This session will delve into the significance of ensuring devices are thoroughly dried before storage and use to prevent microbial proliferation, corrosion, and compromised disinfection and/or sterility.[1-5]
Key focus areas will include:

- **The impact of residual moisture on microbial growth and disinfection and/or sterility efficacy.[10]**
- **Techniques and technologies for achieving complete drying, including automated systems and manual methods.[11-15]**
- **Storage standards for sterile and non-sterile items, addressing environmental controls shelving systems, and segregation.[11-15]**
- **Handling practices that maintain sterility assurance levels (SAL) and prevent recontamination post-disinfection and/or sterilization.[11-15]**
- **Relevant compliance frameworks and how facilities can audit, monitor, and document drying and storage practices.[11-15]**

This chapter will provide insights into building reliable workflows and infrastructure that support safe, compliant, and efficient management of medical devices after cleaning and sterilization.

Drying Techniques:

- Air Drying
- Mechanical Drying
- HEPA-Filtered Air

Best practice: Use automated systems validated for both cleaning and drying.

Image source: St George Endoscopy Department - drying cabinet - courtesy Mr David Bellamy, Sydney, Australia, 2025 Google photo search "flexible endoscope drying cabinet" access on 20250522 https://www.aorn.org/outpatient-surgery/article/2022-September-endoscope-cabinets **Source:** ISO 15883-4:2008 - Washer-disinfectors for thermolabile endoscopes https://www.iso.org/standard/63696.html / GENCA Guidelines 2025 (Australia), https://www.genca.org/public/5/files/-Nurses%20info/IPCE%202021_Feb2022update.pdf / AAMI ST91:2021 (USA), https://www.aami.org/ST91 / AS 5369:2023 (Australia) - Reprocessing of reusable medical devices in health service organizations https://www.standards.org.au/blog/spotlight-on-as-5369-2023

Drying and storage are more than logistical steps. They protect the sterile state and must be handled with as much care as sterilization itself.

A wet endoscope is a contamination risk, not a ready device. Residual moisture creates a perfect environment for microbial growth, especially in long, narrow channels. If it's not dry, it's not safe.

Image source: Google Search https://img.hpnonline.com/files/base/ebm/hpn/image/2023/10/16x9/Cygnus_Medical_Oasis_flexible_endoscope_transport_tray.65201c8317339.png?auto=format,compress&fit=max&q=45&w=640&width=640

Topic • 03

Microbiological Surveillance and Quality Assurance

Microbiological surveillance plays a vital role in verifying the effectiveness of cleaning, disinfection, and sterilization processes within healthcare facilities. This session will examine how routine monitoring and quality assurance practices ensure compliance with national and international standards, mitigate infection risks, and promote patient safety.[1-4]

Microbiological surveillance and QA systems give us early warnings and ongoing validation that our processes are safe and effective. Compliance will only increase with the release of the new ISO 25224.

Image source: Google photo search https://5.imimg.com/data5/SELLER/Default/2023/4/304297764/RA/OB/CV/28132938/bacterial-identification-service.jpg

Topics covered will include:

- **Methods of microbiological surveillance in sterile processing environments, including surface sampling, air monitoring, and water testing.**[1-6]
- **The role of indicators, bioburden testing, and environmental monitoring in validating reprocessing outcomes.**[1-6]
- **Integrating microbiological data into a facility's quality management system for continuous improvement.**[1-6]
- **Documentation, corrective actions, and audit readiness as part of a robust quality assurance framework.**[1-6]

A key focus will be on the emerging **ISO/AWI 25224** standard. Sterilization of health care products. Microbiological methods for testing of reprocessing procedures for medical devices.[5] Currently under development, this standard aims to provide structured guidance on using microbiological methods to test the efficacy of reprocessing procedures, offering a harmonized approach to verifying that reusable medical devices are consistently rendered safe for reuse.[6]

This section will provide practical insights into how microbiological surveillance supports regulatory compliance and how facilities can begin aligning with future standards like ISO/AWI 25224 to strengthen their infection prevention programs.[6]

If you're not testing, you're just guessing.

Microbiological surveillance isn't extra, it's evidence.

It proves your process works, or warns you when it doesn't.

Image source: Google photo search "quality assurance", accessed on 20250422, https://www.sofeast.-com/wp-content/uploads/2019/01/quality-assurance-diagram-1024x682.png.webp

QA Systems in Endoscope Reprocessing:

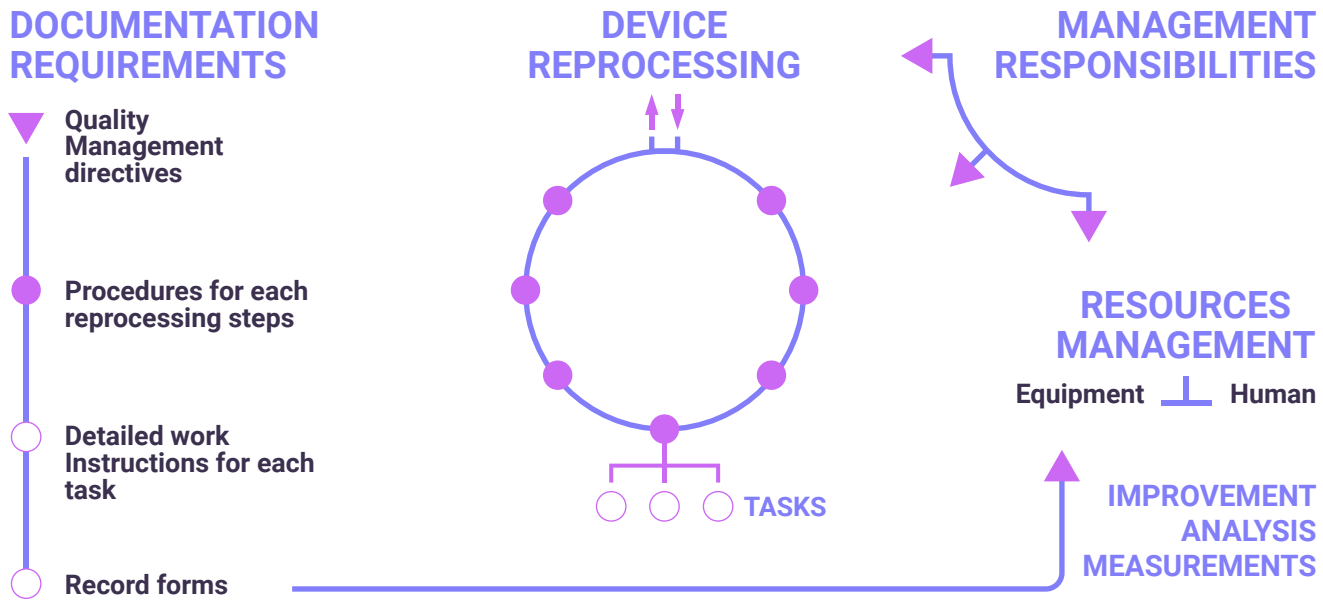


Image source: WFHSS Guidelines – Chapter 9 - Flexible endoscopy reprocessing principles - https://guidelines.wfhss.com/wp-content/uploads/2024/07/graphic_1.png

Topic • 04

Competency, Documentation, and Traceability[1-5]

Competency, documentation, and traceability are foundational pillars of safe, compliant, and high-quality sterilization services. This session explores how well-trained personnel, accurate recordkeeping, and robust tracking systems contribute to patient safety, process validation and audit readiness.[1-5]

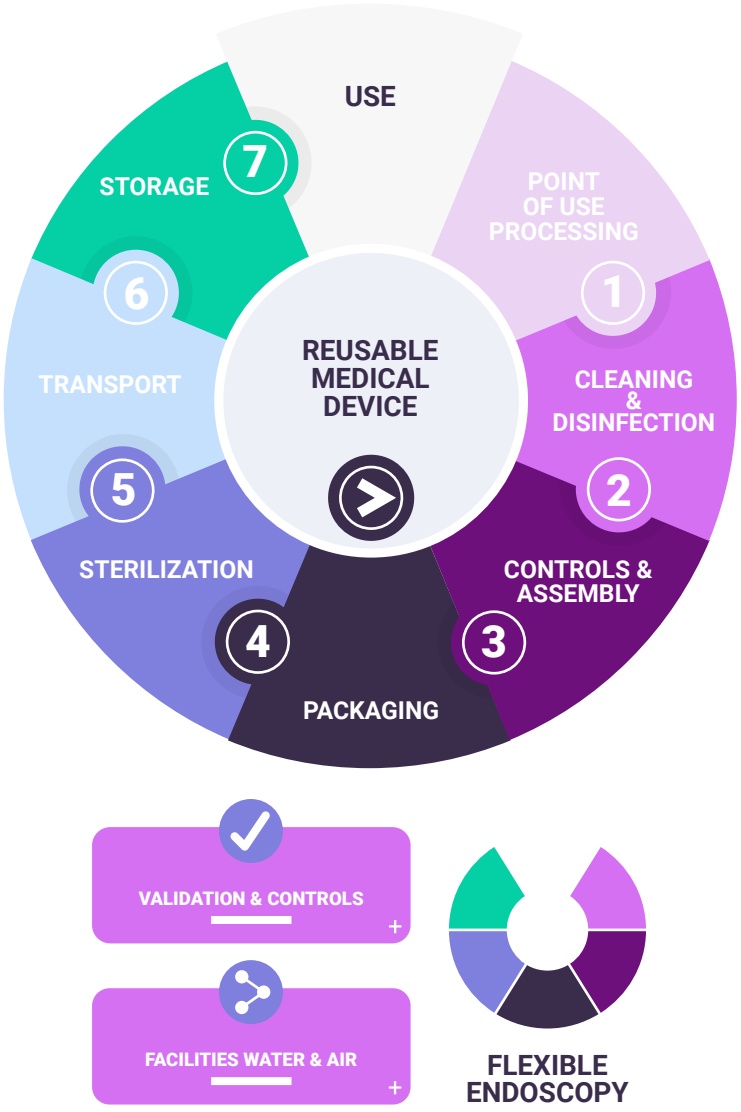


Image source: WFHSS Guidelines – Chapter 9 - Flexible endoscopy reprocessing principles - https://guidelines.wfhss.com/wp-content/uploads/2024/07/graphic_1.png

Participants will gain insights into:

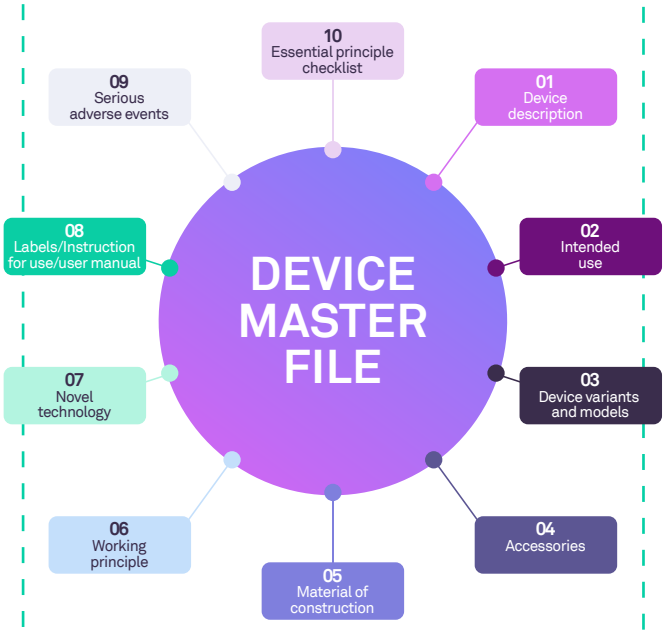
- **The importance of competency-based training and assessment, aligned with national qualifications, and the need for ongoing professional development.[1-5]**
- **Strategies for maintaining accurate documentation to demonstrate process compliance, support incident investigations, and meet legislative and accreditation standards.[1-5]**
- **Methods of achieving full instrument and cycle traceability, including manual and electronic tracking systems, barcode/RFID technologies, and linkages to patient records.[1-5]**
- **The role of documentation and traceability in managing recalls, audits, and root cause analyses.[1-5]**

This section will provide practical guidance for building a culture of accountability and continuous improvement through structured workforce capability, transparent records, and end-to-end traceability.

Sterile assurance doesn't come from machines, it comes from people. Competency, documentation, and traceability are your frontline defense. If it's not trained, traced, and recorded, it did not happen.

None of this works without trained, competent staff and meticulous documentation. Everything must be traceable, auditable, and defensible for both safety and compliance.

Documentation Essentials



- What Needs to Be Documented
- Daily Checklists
- Legal and Accreditation Value

Image source: Google search "documents required for device reprocessing" 22/02/2025 https://pharmaguddu.com/documents-required-for-class-a-medical-device/

Traceability Systems

- **Why Traceability Matters:**

Ensures that every instrument can be tracked from use to reprocessing and back.

- **What Should Be Traceable:**

Patient and procedure links to instruments and sterilization load.
Operator initials, sterilizer number, and cycle ID.

- **Tools and Technology:**

Use of barcoding, RFID tags, or manual tracking sheets.
Digital traceability systems improve accuracy and retrieval speed.

"If you can't trace it, you can't trust it."

Source: ISO 15883-4:2008 - Washer-disinfectors for thermolabile endoscopes, https://www.iso.org/standard/63696.html / GENCA Guidelines 2025 (Australia) https://www.genca.org/public/5/files/Nurses%20info/IPCE%202021_Feb2022update.pdf / AAMI ST91:2021 (USA), https://www.aami.org/ST91 / AS 5369:2023 (Australia) - Reprocessing of reusable medical devices in health service organizations https://www.standards.org.au/blog/spotlight-on-as-5369-2023

Resume

Enhanced Cleaning and Pre-Cleaning Protocols

Effective pre-cleaning and enhanced cleaning are the first and most critical steps in the decontamination process. Without thorough soil removal at the point of use, no disinfection or sterilization method can be relied upon to ensure patient safety.

Prompt, consistent, and standardised cleaning practices not only prevent biofilm formation but also protect equipment integrity, reduce infection risks, and form the foundation of compliant, high-quality reprocessing workflows.[1-5]

Drying and Storage Requirements

Thorough drying and proper storage are essential for maintaining the cleanliness integrity of endoscope devices. Moisture is a key contributor to microbial survival and device damage.

By ensuring items are completely dry before sterilization or storage, and by managing storage environments according to standards, facilities can prevent recontamination, extend device life, and safeguard patient outcomes.[1-5]

Microbiological Surveillance and Quality Assurance

Microbiological surveillance is not just a compliance task—it's a proactive quality assurance strategy that verifies the effectiveness of cleaning, disinfection, and sterilization processes.

Incorporating routine monitoring, documentation, and alignment with emerging standards like ISO/AWI 25224 strengthens infection control, supports continuous improvement, and ensures patient safety through evidence-based validation of reprocessing practices.[6]

Competency, Documentation, and Traceability

Competent staff, accurate documentation, and reliable traceability systems are the backbone of safe and compliant sterilization services.

Ongoing training, detailed recordkeeping, and complete tracking from reprocessing to patient use ensure accountability, support audit readiness, and enable rapid response in the event of an incident, ultimately protecting both patients and healthcare workers.[1-5]

Take home messages

Effective pre-cleaning and enhanced cleaning are essential for decontamination, ensuring patient safety by preventing biofilm, protecting equipment, and supporting high-quality reprocessing workflows.

Thorough drying and proper storage of endoscope devices are crucial for preventing microbial survival, device damage, recontamination, and ensuring patient safety.

Microbiological surveillance is a proactive quality assurance approach that ensures effective reprocessing and patient safety through routine monitoring and alignment with evolving standards.

Skilled staff, precise records, and full traceability ensure safe, compliant sterilization services, support audit readiness, and enable fast responses to incidents protecting patients and healthcare workers.

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Sources:

1.ISO 15883-4:2008 - Washer-disinfectors for thermolabile endoscopes - https://www.iso.org/standard/63696.html 2.GENCA Guidelines 2025 (Australia) - https://www.genca.org/public/5/files/Nurses%20info/IPCE%202021_Feb2022update.pdf 3.AAMI ST91:2021 (USA) - https://www.aami.org/ST91 4. AS 5369:2023 (Australia) - Reprocessing of reusable medical devices in health service organizations - https://www.standards.org.au/blog/spotlight-on-as-5369-2023 5.Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), Disinfection of Healthcare Equipment (pag.6)- https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html 6. ISO/AWI 25224 standard — Sterilization of health care products — Microbiological methods for testing of reprocessing procedures for medical devices. - https://www.iso.org/standard/89497.html 7. Mishra A, Aggarwal A, Khan F. Medical Device-Associated Infections Caused by Biofilm-Forming Microbial Pathogens and Controlling Strategies. Antibiotics (Basel). 2024 Jul 4;13(7):623. doi: 10.3390/antibiotics13070623. PMID: 39061305; PMCID: PMC11274200. 8.Rather MA, Gupta K, Mandal M. Microbial biofilm: formation, architecture, antibiotic resistance, and control strategies. Braz J Microbiol. 2021 Dec;52(4):1701-1718. doi: 10.1007/s42770-021-00624-x. Epub 2021 Sep 23. PMID: 34558029; PMCID: PMC8578483. 9.Rutala WA, Gergen MF, Sickbert-Bennett EE, Weber DJ. Comparative evaluation of the microbicidal activity of low-temperature sterilization technologies to steam sterilization. Infect Control Hosp Epidemiol. 2020 Apr;41(4):391-395. doi: 10.1017/ice.2020.2. Epub 2020 Feb 26. PMID: 32098638. 10.Ofstead CL, Heymann OL, Quick MR, Eiland JE, Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multisite study of endoscope drying effectiveness. Am J Infect Control. 2018 Jun;46(6):689-696. doi: 10.1016/j.ajic.2018.03.002. Epub 2018 Mar 30. PMID: 29609854. 11.ISO 15883-4:2008 - Washer-disinfectors for thermolabile endoscopes - https://www.iso.org/standard/63696.html 12.3. GENCA Guidelines 2025 (Australia), https://www.genca.org/public/5/files/Nurses%20info/IPCE%202021_Feb2022update.pdf 13.4. AAMI ST91:2021 (USA), https://www.aami.org/ST91 14.5. AS 5369:2023 (Australia) - Reprocessing of reusable medical devices in health service organizations 15.https://www.standards.org.au/blog/spotlight-on-as-5369-2023

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