

Non-Critical Device Reprocessing

This domain performs a comprehensive assessment of non-critical device reprocessing activities performed at your facility as it currently functions.

Policy and Procedure

1a - Does the facility have policies and standard operating procedures related to non-critical device reprocessing?

- Yes
- No
- Unsure

1b - What is included in the non-critical device reprocessing policy and SOPs?

- Spaulding classification
- Two-step cleaning and disinfection process
- Approved solutions or products for low-level disinfection
- Cleaning and disinfection at point of care
- Contact time
- Clear designations of non-critical device reprocessing responsibilities
- Device maintenance protocols
- Education and training requirements
- None of the above
- Other

General Practice

2 - When do non-critical devices undergo low-level disinfection?

- After each patient use (point of care)
- When visibly soiled
- Routine/ scheduled device cleaning
- Other

3 - Does facility protocol clearly designate a responsible party to clean and disinfect reusable non-critical patient care devices?

- Yes
- No
- Unsure

4 - Are germicidal wipes for non-critical device reprocessing available at point of use?

- Yes
- No
- Unsure

5 - Are healthcare personnel aware of the required contact time for the germicidal wipes within the facility?

- Yes
- No
- Unsure

6 - Does the facility utilize a germicidal wipe with a short contact time (less than 5 minutes) in order to improve adherence to cleaning and disinfection?

- Yes
- No
- Unsure

7 - Does the facility have a protocol for scenarios where the manufacturer's IFU does not recommend the use of the disinfectants in use at your facility?

- Yes
- No
- Unsure

Single Use Devices

8 - Devices labeled for single use by the manufacturer are discarded after use.

- Always
- Often
- Rarely
- Never

9 - Devices labeled for single use by the manufacturer are not used for more than one patient.

- Always
- Often
- Rarely
- Never

10 - If there are no manufacturer instructions for cleaning and disinfection, are the devices used for more than one patient?

- Yes, devices without instructions for cleaning and disinfection may be used for more than one patient
- No, devices without instructions for cleaning and disinfection are discarded after a single use
- Unsure

11 - Are risk assessments performed in the above scenarios where manufacturer IFUs conflict with facility reprocessing options?

- Yes
- No
- Unsure

Education & Training

12 - Does the facility have a competency-based training program for non-critical device reprocessing?

- Yes
- No
- Unsure

13a - Who receives non-critical device reprocessing training and education?

- Clinical Healthcare Personnel

- Ancillary Services
- Non-clinical Healthcare Personnel
- Clinical Support
- Students & Trainees
- Volunteers
- None
- Other

13b - What is included in non-critical device reprocessing training and education?

- Spaulding classification
- PPE for low-level disinfection
- Cleaning and disinfection at point of use
- Two-step cleaning and disinfection for non-critical devices
- Visual inspection
- Storage
- Documentation
- Wet time
- Quality control
- Maintenance
- None of the above
- Other

14 - What frequency is device reprocessing training and education provided?

- Upon hire
- Annually
- When new equipment and protocols are introduced
- As remediation for compliance failure
- Targeted improvement efforts
- None

15 - Are personnel required to demonstrate competency upon completion of training?

- Yes
- No
- Unsure

16 - Does the facility maintain documentation for device reprocessing training and education?

- Yes
- No
- Unsure

Audit & Feedback

17 - Does the facility audit adherence to non-critical device reprocessing procedures?

- Yes
- No
- Unsure

18 - How are non-critical device audits performed?

- Direct observation

- ATP tracking
- Blacklight
- Culture-based methods
- None
- Other

19 - Are device reprocessing audits performed in all areas where device reprocessing occurs?

- Yes- all areas
- No- not all areas

20 - Do auditors provide immediate real-time feedback to healthcare personnel in the moment?

- Yes
- No
- Unsure

Answer Key

Policy and Procedure

1a - Does the facility have policies and standard operating procedures related to non-critical device reprocessing?

Yes - Preferred

No

1b - What is included in the non-critical device reprocessing policy and SOPs? (**Select all preferred options**)

Spaulding classification - **Preferred**

Two-step cleaning and disinfection process - **Preferred**

Approved solutions or products for low-level disinfection - **Preferred**

Cleaning and disinfection at point of care - **Preferred**

Contact time - **Preferred**

Clear designations of non-critical device reprocessing responsibilities - **Preferred**

Device maintenance protocols - **Preferred**

Education and training requirements - **Preferred**

None of the above

General Practice

2 - When do non-critical devices undergo low-level disinfection? (**Select all preferred options**)

After each patient use (point of care) - **Preferred**

When visibly soiled - **Preferred**

Routine/ scheduled device cleaning - **Preferred**

Other

3 - Does facility protocol clearly designate a responsible party to clean and disinfect reusable non-critical patient care devices?

Yes - Preferred

No

Unsure

4 - Are germicidal wipes for non-critical device reprocessing available at point of use?

Yes - Preferred

No

Unsure

5 - Are healthcare personnel aware of the required contact time for the germicidal wipes within the facility?

Yes - Preferred

No

Unsure

6 - Does the facility utilize a germicidal wipe with a short contact time (less than 5 minutes) in order to improve adherence to cleaning and disinfection?

Yes - Preferred

No

Unsure

7 - Does the facility have a protocol for scenarios where the manufacturer IFU does not recommend the use of the disinfectants in use at your facility?

Yes - Preferred

No

Unsure

Single Use Devices

8 - Devices labeled for single use by the manufacturer are discarded after use.

Always - Preferred

Often

Rarely

Never

9 - Devices labeled for single use by the manufacturer are not used for more than one patient.

Always - Preferred

Often

Rarely

Never

10 - If there are no manufacturer instructions for cleaning and disinfection, are the devices used for more than one patient?

Yes, devices without instructions for cleaning and disinfection may be used for more than one patient

No, devices without instructions for cleaning and disinfection are discarded after a single use - Preferred

Unsure

11 - Are risk assessments performed in the above scenarios where manufacturer IFUs conflict with facility reprocessing options?

Yes - Preferred

No

Unsure

Education & Training

12 - Does the facility have a competency-based training program for non-critical device reprocessing?

Yes - Preferred

No

Unsure

13a - Who receives non-critical device reprocessing training and education? (**Select all preferred options**)

Clinical Healthcare Personnel - Preferred

Ancillary Services - Preferred

Non-clinical Healthcare Personnel - Preferred

Clinical Support - Preferred

- Students & Trainees - **Preferred**
- Volunteers - **Preferred**
- None
- Other

13b - What is included in non-critical device reprocessing training and education? (**Select all preferred options**)

- Spaulding classification - **Preferred**
- PPE for low-level disinfection - **Preferred**
- Cleaning and disinfection at point of use - **Preferred**
- Two-step cleaning and disinfection for non-critical devices - **Preferred**
- Visual inspection - **Preferred**
- Storage - **Preferred**
- Documentation - **Preferred**
- Wet time - **Preferred**
- Quality control - **Preferred**
- Maintenance - **Preferred**
- None of the above
- Other

14 - What frequency is device reprocessing training and education provided? (**Select all preferred options**)

- Upon hire - **Preferred**
- Annually - **Preferred**
- When new equipment and protocols are introduced - **Preferred**
- As remediation for compliance failure - **Preferred**
- Targeted improvement efforts - **Preferred**
- None

15 - Are personnel required to demonstrate competency upon completion of training?

- Yes - Preferred**
- No
- Unsure

16 - Does the facility maintain documentation for device reprocessing training and education?

- Yes - Preferred**
- No
- Unsure

Audit & Feedback

17 - Does the facility audit adherence to non-critical device reprocessing procedures?

- Yes - Preferred**
- No
- Unsure

18 - How are non-critical device audits performed? (**Select all preferred options**)

- Direct observation - **Preferred**
- ATP tracking - **Preferred Optional**

- Blacklight - ***Preferred Optional***
- Culture-based methods - ***Preferred Optional***
- None
- Other

19 - Are device reprocessing audits performed in all areas where device reprocessing occurs?

- Yes- all areas - ***Preferred***
- No- not all areas

20 - Do auditors provide immediate real-time feedback to healthcare personnel in the moment?

- Yes - ***Preferred***
- No
- Unsure

Guidance

Policy and Procedure

Core Element Description: Assessment of policies and procedures related to device reprocessing practices within the facility.

Free Access: Regulatory

Centers for Medicare and Medicaid Services. (2026). State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_a_hospitals.pdf

Centers for Medicare and Medicaid Services. (n.d.) Hospital infection control worksheet

<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>

General Practice

Core Element Description: Assessment of non-critical device reprocessing practice and organization within the facility.

Free Access: Regulatory

Centers for Medicare and Medicaid Services. (n.d.) Hospital infection control worksheet

<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>

Free Access: Guidelines

Rutala, W.A., Weber, D.L., and the Healthcare Infection Control Practices Advisory Committee. (2024, June). Guideline for disinfection and sterilization in healthcare facilities, 2008.

<https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf>

Single Use Devices

Core Element Description: Assessment of the facility's management of single-use devices.

Free Access: Regulatory

Food and Drug Administration. 2001. Labeling recommendations for single-use devices reprocessed by third parties and hospitals; Final guidance for Industry and FDA.

<https://www.fda.gov/media/71405/download>

Free Access: Guidelines

Rutala, W.A., Weber, D.L., and the Healthcare Infection Control Practices Advisory Committee. (2024, June). Guideline for disinfection and sterilization in healthcare facilities, 2008.

<https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf>

Education & Training

Core Element Description: Assessment of education and training of healthcare personnel to appropriately perform device reprocessing as it relates to their job role.

Free Access: Regulatory

Centers for Medicare and Medicaid Services. (n.d.) Hospital infection control worksheet
<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>

Audit & Feedback

Core Element Description: Assessment of audit and feedback practices regarding non-critical, semi-critical, and critical device reprocessing.

Free Access: Regulatory

Centers for Medicare and Medicaid Services. (n.d.) Hospital infection control worksheet
<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>

Free Access: Guidelines

Centers for Disease Control and Prevention. (2002) Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51.
<https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

Free Access: Resources

Washer, L., Gilmartin, H.M., Olmstead, R., Centers for Disease Control and Prevention. (n.d.) Hand Hygiene: Education, Monitoring, and Feedback. <https://www.cdc.gov/infection-control/media/pdfs/Strive-HH102-508.pdf>

Additional Guidance

Free Access: Regulatory

Centers for Medicare and Medicaid Services. (2015). Alert related to outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) during gastrointestinal endoscopy, particularly endoscopic retrograde cholangiopancreatography (ERCP). <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-32.pdf>

Food and Drug Administration. (2015) Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/media/80265/download>

United States Environmental Protection Agency. (2025, September 11). Selected EPA-registered disinfectants. <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>

Free Access: Guidelines

Rutala, W.A., Weber, D.L., and the Healthcare Infection Control Practices Advisory Committee. (2024, June). Guideline for disinfection and sterilization in healthcare facilities, 2008. <https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf>

Free Access: Resources

Centers for Disease Control and Prevention. (2021, December 21.) Quick Observation Tools (QUOTs) for Infection Prevention. <https://www.cdc.gov/infection-control/media/pdfs/All-Quick->

[Observation-Tools-P.pdf](#)

Purchase Required: Guidelines

Association of Perioperative Registered Nurses. (2021). High-level disinfection. Guidelines for perioperative practice. Denver, CO: AORN, Inc. <https://www.aorn.org/guidelines-resources/guidelines-for-perioperative-practice>

Association of perioperative Registered Nurses. (2021). Environmental cleaning. Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. <https://www.aorn.org/guidelines-resources/guidelines-for-perioperative-practice>

Association of Perioperative Registered Nurses. (2021). Flexible endoscopes. Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. <https://www.aorn.org/guidelines-resources/guidelines-for-perioperative-practice>

Association of Perioperative Registered Nurses. (2021). Instrument cleaning. Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. <https://www.aorn.org/guidelines-resources/guidelines-for-perioperative-practice>

Association of Perioperative Registered Nurses. (2021). Sterilization. Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. <https://www.aorn.org/guidelines-resources/guidelines-for-perioperative-practice>

Purchase Required: Standards

Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI ST 58: 2013 (R2018). Chemical Sterilization and High-Level Disinfection in Healthcare Facilities. Arlington, VA: AAMI. <https://webstore.ansi.org/standards/aami/ansiaamist582013r2018>

Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI ST 91:2015. Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: AAMI. <https://webstore.ansi.org/Standards/AAMI/ANSIAAMIST912021>

Purchase Required: Resources

Alvino, R.T., & Ricupito, G.T. Reprocessing single-use devices. In Boston K.M., et al, eds. APIC Text. <https://text.apic.org/toc/basic-principles-of-infection-prevention-practice/reprocessing-single-use-devices>

Jefferson, J., & Young, M. (2016, April 25). Sterile processing. In Boston K.M., et al, eds. APIC Text. <https://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing>

Jinadatha, C., & Bridges, A. (2020, December 21). Cleaning, disinfection, and sterilization. In Boston K.M., et al, eds. APIC Text. <https://text.apic.org/toc/basic-principles-of-infection-prevention-practice/cleaning-disinfection-and-sterilization>