Semi-Critical Device Reprocessing

This domain performs a comprehensive assessment of semi-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 semi-critical device reprocessing?

- ☐ Yes
- ☐ No
- ☐ Unsure

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

- ☐ Spaulding classification
- ☐ Device transport
- ☐ Borrowed instrumentation or devices
- ☐ Device maintenance protocols
- ☐ Device reprocessing failure protocol
- ☐ HLD IFU adherence process
- ☐ Required PPE for HLD
- ☐ Approved solutions for HLD
- ☐ HLD Pre-cleaning
- ☐ HLD leak testing- if applicable to the device
- ☐ HLD manual cleaning
- ☐ HLD mechanical cleaning
- ☐ HLD Visual Inspection
- ☐ High-level disinfection process preparation
- ☐ HLD active disinfection
- ☐ HLD device storage
- ☐ HLD documentation requirements
- ☐ None of the above
- ☐ Other

General Practice

2 - High-level disinfection is performed:

- ☐ Onsite (centralized or decentralized)
- ☐ Off-site
- ☐ Combination of onsite and offsite
- ☐ None - HLD is not required at my facility

3 - Is the service that performs off-site HLD compliant with all state, federal, and regulatory bodies?

- ☐ Yes
- ☐ No
- ☐ Unsure

4 - Are items pre-cleaned and moistened prior to off-site transport?
- ☐ Yes
- ☐ No
- ☐ Unsure

5 - How are items prepared for off-site transport?
- ☐ Pre-cleaned per manufacturer IFU
- ☐ Placed in puncture-resistant and lockable biohazard container
- ☐ Items kept wet with enzymatic or transport gel
- ☐ None
- ☐ Other

6 - Are manufacturer IFUs available to staff at point of use to ensure manufacturer's instructions are followed for HLD?
- ☐ Yes
- ☐ No
- ☐ Unsure

7 - Is the IPC program aware of all types of high-level disinfection equipment in use at the facility (including clinics and satellite departments)
- ☐ Yes
- ☐ No
- ☐ Unsure

8 - Do semi-critical items undergo, at a minimum, high-level disinfection prior to reuse?
- ☐ Yes
- ☐ No
- ☐ Unsure

9 - Are flexible endoscopes inspected for damage and leak tested in each reprocessing cycle?
- ☐ Yes
- ☐ No
- ☐ Unsure

10 - Are items thoroughly pre-cleaned according to the manufacturer's IFU prior to HLD?
- ☐ Yes
- ☐ No
- ☐ Unsure

11 - Are items visually inspected for residual soil prior to HLD?
- ☐ Yes
- ☐ No
- ☐ Unsure

12 - Do instruments with lumens (e.g., endoscopes) undergo pre-cleaning of all channels using separate cleaning brushes approved by the manufacturer?
- ☐ Yes
- ☐ No
- ☐ Unsure

13a - Are all IFUs for the enzymatic followed by staff? (e.g., correct temperatures, dilution, soaking, etc.)
- ☐ Yes
- ☐ No
- ☐ Unsure

13b - Is the enzymatic or detergent used for cleaning discarded according to the manufacturer's IFU (typically after each use)?
- ☐ Yes
- ☐ No
- ☐ Unsure

14a - What brushes are used for cleaning at the facility?
- ☐ Single use
- ☐ Reusable
- ☐ Both
- ☐ Neither

14b - Are single-use brushes discarded after every use?
- ☐ Yes
- ☐ No
- ☐ Unsure

14c - Are reusable brushes cleaned and disinfected (HLD or sterilized) per manufacturer IFU at least daily?
- ☐ Yes
- ☐ No
- ☐ Unsure

15 - If automated reprocessing equipment is used, are the manufacturer's recommended connectors/adapters used to ensure all endoscope channels are appropriately disinfected?
- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Not Applicable

16 - Do devices undergo disinfection for the appropriate length of time according to the manufacturer's IFU?
- ☐ Yes
- ☐ No
- ☐ Unsure

17 - Are devices rinsed with sterile, filtered, or tap water followed by an ethyl or isopropyl alcohol rinse in accordance with the manufacturer's IFU?
- ☐ Yes
- ☐ No
- ☐ Unsure

18 - Are semi-critical devices thoroughly dried prior to reuse?
- ☐ Yes
- ☐ No
- ☐ Unsure

19 - How are endoscopes or other channeled devices dried at the facility?
- ☐ Electronic drying cabinet or AER
- ☐ Hang dry vertically or horizontally per IFU - Correct
- ☐ Hang dry in well-ventilated area or cabinet
- ☐ Forced medical air/ purged air per IFU
- ☐ No formal drying process
- ☐ Not applicable, channeled devices are not used at the facility
- ☐ Other

20 - Do semi-critical devices undergo routine maintenance?
- ☐ Yes
- ☐ No
- ☐ Unsure

21 - Does the facility maintain documentation of semi-critical device maintenance?
- ☐ Yes
- ☐ No
- ☐ Unsure

22a - Does the facility maintain thorough documentation of all HLD processed in all areas where HLD occurs? (including clinics and satellite departments)
- ☐ Yes
- ☐ No
- ☐ Unsure

22b - What is included in HLD documentation?
- ☐ Pre-cleaning with enzymatic detergent per IFU
- ☐ Leak testing- if applicable
- ☐ Lumen cleaning if applicable
- ☐ Chemical solution used per IFU
- ☐ Visual inspection
- ☐ Preparation of HLD chemicals per IFU
- ☐ Chemical replacement per IFU
- ☐ Lot numbers
- ☐ Expiration dates
- ☐ Temperature limits
- ☐ Length of reprocessing cycle
- ☐ Storage
- ☐ Other

23a - After HLD, are semi-critical devices stored in a standardized manner to protect them from damage and contamination?
- ☐ Yes
- ☐ No

☐ Unsure

23b - How are semi-critical devices stored?
☐ Professional-grade cabinets labeled by manufacturer for endoscope storage
☐ Clean storage areas, e.g., in storage rooms, procedure bay/ OR - Correct
☐ Covered and/or labeled- "Clean" and/or "Not Sterile" - Correct
☐ Semi-critical devices are packed or wrapped sterile.
☐ No standardized process for semi-critical device storage
☐ Other

Single Use Devices

24 - Devices labeled for single use by the manufacturer are discarded after use.
☐ Always
☐ Often
☐ Rarely
☐ Never

25 - Devices labeled for single use by the manufacturer are not used for more than one patient.
☐ Always
☐ Often
☐ Rarely
☐ Never

26 - 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

27 - Does the facility have a protocol if a conflict is identified between the device IFU and what is available for reprocessing at your institution?
☐ Yes
☐ No
☐ Unsure

28 - Are risk assessments performed in the above scenarios where manufacturer IFUs conflict with hospital reprocessing options?
☐ Yes
☐ No
☐ Unsure

Reprocessing Failure

29 - Does the facility have a protocol for device reprocessing failure events?
☐ Yes
☐ No
☐ Unsure

30 - Does the protocol include a defined process for immediate mitigation strategies in reprocessing failure events?
- ☐ Yes
- ☐ No
- ☐ Unsure

31a - Are investigations performed in reprocessing failure events?
- ☐ Yes
- ☐ No
- ☐ Unsure

31b - What is included in the reprocessing failure investigation?
- ☐ Reload to identify potential user error
- ☐ Quarantine loads until root cause is identified
- ☐ Equipment in question is removed from service
- ☐ Determine cause of failure
- ☐ Consultation with the Infection Preventionist if a contaminated instrument was used on a patient
- ☐ Other

32 - Does the facility have a process algorithm or decision tree for reprocessing failures, including potential pathways that reach a patient?
- ☐ Yes
- ☐ No
- ☐ Unsure

Device Tracking

33 - Does the facility have a system in place to identify which devices were used on a patient during procedures?
- ☐ Yes
- ☐ No
- ☐ Unsure

34b - What systems are in place to identify devices and accessories used on patients?
- ☐ Device numbers linked in the electronic health record
- ☐ Device numbers written in the paper chart
- ☐ Paper log in procedural areas
- ☐ Electronic record keeping in device reprocessing (e.g., scan/ case cart system)
- ☐ No system for tracking exists
- ☐ Other

34a - Does the facility track all components and accessories of reprocessible devices that may be used on patients?
- ☐ Yes
- ☐ No
- ☐ Unsure

Device Procurement

35a - Does the facility have a formalized device procurement and purchasing process?
- ☐ Yes
- ☐ No
- ☐ Unsure

35b - Is the IPC program consulted when new devices or products are introduced?
- ☐ Always
- ☐ Often
- ☐ Rarely
- ☐ Never

Education & Training

36 - Does the facility have a competency-based training program for semi-critical device reprocessing?
- ☐ Yes
- ☐ No
- ☐ Unsure

37a - Who receives semi-critical device reprocessing training and education as it pertains to their job role?
- ☐ Physicians
- ☐ Advanced Practice Providers
- ☐ Nurses
- ☐ Nursing support
- ☐ Device Reprocessing Personnel
- ☐ Surgical Services Personnel
- ☐ Department-specific reprocessing personnel
- ☐ Students & trainees
- ☐ None of the above
- ☐ Other

37b - What is included in semi-critical device reprocessing training and education?
- ☐ Spaulding classification
- ☐ PPE for HLD
- ☐ Transport of biohazardous devices from point of use
- ☐ Manufacturer provided education and training
- ☐ IFU checklists
- ☐ Pre-cleaning
- ☐ Leak-testing if applicable
- ☐ Manual cleaning
- ☐ Mechanical cleaning devices
- ☐ Visual inspection
- ☐ Disinfection
- ☐ Packaging
- ☐ Storage
- ☐ Documentation
- ☐ Quality control

☐ Maintenance
☐ None of the above
☐ Other

38 - 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

39 - Are personnel required to demonstrate competency upon completion of training?
☐ Yes
☐ No
☐ Unsure

40 - Does the facility maintain documentation for device reprocessing training and education?
☐ Yes
☐ No
☐ Unsure

Audit & Feedback

41 - Does the facility audit adherence to semi-critical reprocessing procedures?
☐ Yes
☐ No
☐ Unsure

42 - How are semi-critical device audits performed?
☐ Direct observation following checklist/ IFU
☐ ATP tracking
☐ Blacklight
☐ Culture-based methods
☐ Disinfection log review
☐ None of the above
☐ Other

43 - Are device reprocessing audits performed in all areas where device reprocessing occurs?
☐ Yes- all areas
☐ No- not all areas

44a - Does the facility provide feedback from the audits to healthcare personnel?
☐ Yes
☐ No
☐ Unsure

44b - Do auditor(s) provide immediate real-time feedback to healthcare personnel in the moment?
☐ Yes

☐ No
☐ Unsure

45 - Does the IP perform independent audits in all areas where semi-critical device reprocessing occurs?
☐ Yes
☐ No
☐ Unsure

Environment of Care

46 - Does the hospital monitor the HVAC settings of areas where high-level disinfection occurs?
☐ Yes
☐ No
☐ Unsure

47 - Does the Water Management team evaluate and monitor the water quality for HLD areas?
☐ Yes
☐ No
☐ Unsure

48 - If Glutaraldehyde is in use, are safety measures in place? (e.g., monitoring of air exchanges, eye wash stations in room, etc.)
☐ Yes
☐ No
☐ Unsure
☐ Not Applicable

49 - Is there a functional and clear workflow in the HLD area from dirty to clean?
☐ Yes
☐ No
☐ Unsure

50 - In the decontamination area, is there a clearly designated hand washing sink that is separate from the sink used for device cleaning?
☐ Yes
☐ No
☐ Unsure

Answer Key

Policy and Procedure

1a - Does the facility have policies and standard operating procedures related to semi-critical device reprocessing?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

1b - What is included in the semi-critical device reprocessing policy and SOPs? **(Select all preferred options)**
[x] Spaulding classification **- *Preferred***
[x] Device transport **- *Preferred***
[x] Borrowed instrumentation or devices **- *Preferred Optional***
[x] Device maintenance protocols **- *Preferred***
[x] Device reprocessing failure protocol **- *Preferred***
[x] HLD IFU adherence process **- *Preferred***
[x] Required PPE for HLD **- *Preferred***
[x] Approved solutions for HLD **- *Preferred***
[x] HLD Pre-cleaning **- *Preferred***
[x] HLD leak testing- if applicable to the device **- *Preferred***
[x] HLD manual cleaning **- *Preferred***
[x] HLD mechanical cleaning **- *Preferred***
[x] HLD Visual Inspection **- *Preferred***
[x] High-level disinfection process preparation **- *Preferred***
[x] HLD active disinfection **- *Preferred***
[x] HLD device storage **- *Preferred***
[x] HLD documentation requirements **- *Preferred***
[ ] None of the above
[ ] Other

General Practice

2 - High-level disinfection is performed: **(Not Scored – Informational Only)**
[ ] Onsite (centralized or decentralized)
[ ] Off-site
[ ] Combination of onsite and offsite
[ ] None - HLD is not required at my facility

3 - Is the service that performs off-site HLD compliant with all state, federal, and regulatory bodies?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

4 - Are items pre-cleaned and moistened prior to off-site transport?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

5 - How are items prepared for off-site transport? **(Select all preferred options)**
[x] Pre-cleaned per manufacturer IFU **- *Preferred***
[x] Placed in puncture-resistant and lockable biohazard container **- *Preferred***
[x] Items kept wet with enzymatic or transport gel **- *Preferred***
[ ] None
[ ] Other

6 - Are manufacturer IFUs available to staff at point of use to ensure manufacturer's instructions are followed for HLD?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

7 - Is the IPC program aware of all types of high-level disinfection equipment in use at the facility (including clinics and satellite departments)
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

8 - Do semi-critical items undergo, at a minimum, high-level disinfection prior to reuse?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

9 - Are flexible endoscopes inspected for damage and leak tested in each reprocessing cycle?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

10 - Are items thoroughly pre-cleaned according to the manufacturer's IFU prior to HLD?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

11 - Are items visually inspected for residual soil prior to HLD?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

12 - Do instruments with lumens (e.g., endoscopes) undergo pre-cleaning of all channels using separate cleaning brushes approved by the manufacturer?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

13a - Are all IFUs for the enzymatic followed by staff? (e.g., correct temperatures, dilution, soaking, etc.)
[x] Yes - *Preferred*

[ ] No
[ ] Unsure

13b - Is the enzymatic or detergent used for cleaning discarded according to the manufacturer's IFU (typically after each use)?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

14a - What brushes are used for cleaning at the facility? **(Not Scored – Informational Only)**
[ ] Single-use
[ ] Reusable
[ ] Both
[ ] Neither

14b - Are single-use brushes discarded after every use?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

14c - Are reusable brushes cleaned and disinfected (HLD or sterilized) per manufacturer IFU at least daily?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

15 - If automated reprocessing equipment is used, are the manufacturer's recommended connectors/adapters used to ensure all endoscope channels are appropriately disinfected?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure
[ ] Not Applicable

16 - Do devices undergo disinfection for the appropriate length of time according to the manufacturer's IFU?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

17 - Are devices rinsed with sterile, filtered, or tap water followed by an ethyl or isopropyl alcohol rinse in accordance with the manufacturer's IFU?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

18 - Are semi-critical devices thoroughly dried prior to reuse?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

19 - How are endoscopes or other channeled devices dried at the facility? **(Select all preferred options)**
[x] Electronic drying cabinet or AER **- *Preferred***
[x] Hang dry vertically or horizontally per IFU - Correct
[x] Hang dry in a well-ventilated area or cabinet **- *Preferred***
[x] Forced medical air/ purged air per IFU **- *Preferred***
[ ] No formal drying process
[ ] Not applicable, channeled devices are not used at the facility
[ ] Other

20 - Do semi-critical devices undergo routine maintenance?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

21 - Does the facility maintain documentation of semi-critical device maintenance?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

22a - Does the facility maintain thorough documentation of all HLD processed in all areas where HLD occurs? (including clinics and satellite departments)
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

22b - What is included in HLD documentation? **(Select all preferred options)**
[x] Pre-cleaning with enzymatic detergent per IFU **- *Preferred Optional***
[x] Leak testing- if applicable **- *Preferred Optional***
[x] Lumen cleaning if applicable **- *Preferred Optional***
[x] Chemical solution used per IFU **- *Preferred***
[x] Visual inspection **- *Preferred Optional***
[x] Preparation of HLD chemicals per IFU **- *Preferred Optional***
[x] Chemical replacement per IFU **- *Preferred***
[x] Lot numbers **- *Preferred***
[x] Expiration dates **- *Preferred***
[x] Temperature limits **- *Preferred***
[x] Length of reprocessing cycle **- *Preferred***
[x] Storage **- *Preferred Optional***
[ ] Other

23a - After HLD, are semi-critical devices stored in a standardized manner to protect them from damage and contamination?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

23b - How are semi-critical devices stored? **(Select all preferred options)**
[x] Professional-grade cabinets labeled by manufacturer for endoscope storage ***- Preferred***
[x] Clean storage areas, e.g., in storage rooms, procedure bay/ OR - Correct
[x] Covered and/or labeled- "Clean" and/or "Not Sterile" - Correct
[x] Semi-critical devices packed or wrapped sterile. ***- Preferred***
[ ] No standardized process for semi-critical device storage
[ ] Other

Single Use Devices

24 - Devices labeled for single use by the manufacturer are discarded after use.
[x] Always - *Preferred*
[ ] Often
[ ] Rarely
[ ] Never

25 - Devices labeled for single use by the manufacturer are not used for more than one patient.
[x] Always - *Preferred*
[ ] Often
[ ] Rarely
[ ] Never

26 - 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
[x] No, devices without instructions for cleaning and disinfection are discarded after a single use ***- Preferred***
[ ] Unsure

27 - Does the facility have a protocol if a conflict is identified between the device IFU and what is available for reprocessing at your institution?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

28 - Are risk assessments performed in the above scenarios where manufacturer IFUs conflict with hospital reprocessing options?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

Reprocessing Failure

29 - Does the facility have a protocol for device reprocessing failure events?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

30 - Does the protocol include a defined process for immediate mitigation strategies in reprocessing failure events?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

31a - Are investigations performed in reprocessing failure events?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

31b - What is included in the reprocessing failure investigation? **(Select all preferred options)**
[x] Reload to identify potential user error **- *Preferred***
[x] Quarantine loads until root cause is identified **- *Preferred***
[x] Equipment in question is removed from service **- *Preferred***
[x] Determine cause of failure **- *Preferred***
[x] Consultation with the Infection Preventionist if a contaminated instrument was used on a patient **- *Preferred***
[ ] Other

32 - Does the facility have a process algorithm or decision tree for reprocessing failures, including potential pathways that reach a patient?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

Device Tracking

33 - Does the facility have a system in place to identify which devices were used on a patient during procedures?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

34b - What systems are in place to identify devices and accessories used on patients? **(Not Scored – Informational Only)**
[ ] Device numbers linked in the electronic health record
[ ] Device numbers written in the paper chart
[ ] Paper log in procedural areas
[ ] Electronic record keeping in device reprocessing (e.g., scan/ case cart system)
[ ] No system for tracking exists
[ ] Other

34a - Does the facility track all components and accessories of reprocessible devices that may be used on patients?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

Device Procurement

35a - Does the facility have a formalized device procurement and purchasing process?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

35b - Is the IPC program consulted when new devices or products are introduced?
[x] Always **- *Preferred***
[ ] Often **- *Preferred***
[ ] Rarely
[ ] Never

Education & Training

36 - Does the facility have a competency-based training program for semi-critical device reprocessing?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

37a - Who receives semi-critical device reprocessing training and education as it pertains to their job role? **(Select all preferred options)**
[x] Physicians **- *Preferred***
[x] Advanced Practice Providers **- *Preferred***
[x] Nurses **- *Preferred***
[x] Nursing support **- *Preferred***
[x] Device Reprocessing Personnel **- *Preferred***
[x] Surgical Services Personnel **- *Preferred***
[x] Department-specific reprocessing personnel **- *Preferred***
[x] Students & trainees **- *Preferred Optional***
[ ] None of the above
[ ] Other

37b - What is included in semi-critical device reprocessing training and education? **(Select all preferred options)**
[x] Spaulding classification **- *Preferred***
[x] PPE for HLD **- *Preferred***
[x] Transport of biohazardous devices from point of use **- *Preferred***
[x] Manufacturer provided education and training **- *Preferred***
[x] IFU checklists **- *Preferred***
[x] Pre-cleaning **- *Preferred***
[x] Leak-testing if applicable **- *Preferred***
[x] Manual cleaning **- *Preferred***
[x] Mechanical cleaning devices **- *Preferred Optional***
[x] Visual inspection **- *Preferred***
[x] Disinfection **- *Preferred***
[x] Packaging **- *Preferred***
[x] Storage **- *Preferred***
[x] Documentation **- *Preferred***

[x] Quality control **- *Preferred***
[x] Maintenance **- *Preferred***
[ ] None of the above
[ ] Other

38 - What frequency is device reprocessing training and education provided? **(Select all preferred options)**
[x] Upon hire **- *Preferred***
[x] Annually **- *Preferred***
[x] When new equipment and protocols are introduced **- *Preferred***
[x] As remediation for compliance failure **- *Preferred***
[x] Targeted improvement efforts **- *Preferred***
[ ] None

39 - Are personnel required to demonstrate competency upon completion of training?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

40 - Does the facility maintain documentation for device reprocessing training and education?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

Audit & Feedback

41 - Does the facility audit adherence to semi-critical reprocessing procedures?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

42 - How are semi-critical device audits performed? **(Select all preferred options)**
[x] Direct observation following checklist/ IFU **- *Preferred***
[x] ATP tracking **- *Preferred Optional***
[x] Blacklight **- *Preferred Optional***
[x] Culture-based methods **- *Preferred Optional***
[x] Disinfection log review **- *Preferred Optional***
[ ] None of the above
[ ] Other

43 - Are device reprocessing audits performed in all areas where device reprocessing occurs?
[x] Yes- all areas - *Preferred*
[ ] No- not all areas

44a - Does the facility provide feedback from the audits to healthcare personnel?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

44b - Do auditor(s) provide immediate real-time feedback to healthcare personnel in the moment?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

45 - Does the IP perform independent audits in all areas where semi-critical device reprocessing occurs?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

Environment of Care

46 - Does the hospital monitor the HVAC settings of areas where high-level disinfection occurs?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

47 - Does the Water Management team evaluate and monitor the water quality for HLD areas? **(Not Scored – Informational Only)**
[ ] Yes
[ ] No
[ ] Unsure

48 - If Glutaraldehyde is in use, are safety measures in place? (e.g., monitoring of air exchanges, eye wash stations in room, etc.) **(Not Scored – Informational Only)**
[ ] Yes
[ ] No
[ ] Unsure
[ ] Not Applicable

49 - Is there a functional and clear workflow in the HLD area from dirty to clean?
[x] Yes - *Preferred*
[ ] No
[ ] Unsure

50 - In the decontamination area, is there a clearly designated hand washing sink that is separate from the sink used for device cleaning?
[x] 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 semi-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. 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 hospital'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. Guideline for disinfection and sterilization in healthcare facilities, 2008. https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf

Reprocessing Failure

Core Element Description: Assessment of systems in place to identify, mitigate, and respond to a reprocessing failure at the facility.

Free Access: Guidelines

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

Device Tracking

Core Element Description: Assessment of systems in place to identify and track devices within the health system from device reprocessing to storage to point of use.

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

Purchase Required: Standards

Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI ST 79: 2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Arlington, VA: AAMI. https://store.aami.org/s/store#/store/browse/detail/a152E00000A7DU5QAN

Device Procurement

Core Element Description: Assessment of the facility's device procurement programs.

No Guidance Available - *Intentionally left blank*

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

Environment of Care

Core Element Description: Assessment of the environment of care within the Sterile Processing Department.

Free Access: Guidelines

Sehulster LM, Chinn RYW, Arduino MJ, Carpenter J, Donlan R, Ashford D, Besser R, Fields B, McNeil MM, Whitney C, Wong S, Juranek D, Cleveland J. Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago IL; American Society for Healthcare Engineering/American Hospital Association; 2004. https://www.cdc.gov/infection-control/media/pdfs/guideline-environmental-h.pdf?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.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. (2021, December 21). 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. 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 health care 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

Curchoe, R. Reprocess single-use devices. In Boston K.M., et al, eds. APIC Text. 2014 https://text.apic.org/toc/basic-principles-of-infection-prevention-practice/reprocessing-single-use-devices

Jefferson, J., & Young, M. Sterile processing. In Boston K.M., et al, eds. APIC Text. 2014. https://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing

Jinadatha, C., & Bridges, A. Cleaning, disinfection, and sterilization. In Boston K.M., et al, eds. APIC Text. 2014. https://text.apic.org/toc/basic-principles-of-infection-prevention-practice/cleaning-disinfection-and-sterilization