Critical Device Reprocessing

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

Policy & Procedure

1 - Question here
- ☐ Yes
- ☐ No
- ☐ Unsure

1a - Does the facility have policies and standard operating procedures related to critical device reprocessing?
- ☐ Yes
- ☐ No
- ☐ Unsure

1b - What is included in the critical device reprocessing policy and SOPs?
- ☐ Spaulding classification
- ☐ Critical device disinfection process preparation (e.g., pre-cleaning, manual/mechanical cleaning, chemical preparation, etc.)
- ☐ Required PPE for sterilization
- ☐ Approved solutions and settings for sterilization
- ☐ Visual inspection
- ☐ Sterilizer specific monitoring requirements (e.g., temperature, humidity, documentation, indicators, etc.)
- ☐ Sterilization
- ☐ Storage
- ☐ Device transport
- ☐ Device maintenance protocols
- ☐ Single-use and multi-use accessories
- ☐ Device/ instrument purchasing requirements
- ☐ Borrowed instrumentation or devices
- ☐ Device reprocessing failure protocol (e.g., positive indicators, etc.)
- ☐ Special procedures: Creutzfeldt-Jakob disease (CJD), Immediate-use steam sterilization (IUSS), etc.
- ☐ None of the above
- ☐ Other

General Practice

2 - Sterile processing is performed:
- ☐ Onsite (centralized or decentralized)
- ☐ Off-site by hired vendor
- ☐ Combination of onsite and offsite
- ☐ None. Sterile processing is not required at the facility

3 - Is the service that performs off-site sterilization compliant with all state, federal, and regulatory bodies?
- ☐ Yes
- ☐ No
- ☐ Unsure

4 - Are items pre-cleaning 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 a puncture-resistant and lockable biohazard container
- ☐ Manual wiping of the device
- ☐ Items kept wet with enzymatic or transport gel
- ☐ Other

6 - Is the IPC program aware of all types of sterilizers in use at the facility?
- ☐ Yes
- ☐ No
- ☐ Unsure

7 - Are manufacturer IFUs available to staff at the point of use to ensure manufacturer's instructions are followed for sterile processing?
- ☐ Yes
- ☐ No
- ☐ Unsure

8 - Are critical items sterilized prior to each use?
- ☐ Yes
- ☐ No
- ☐ Unsure

9 - Critical items labeled for single-use are:
- ☐ Discarded after each use
- ☐ Reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor AND is cleared by the FDA to reprocess the specific device in question
- ☐ Reprocessed at the facility without FDA authorization
- ☐ Other

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

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

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

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

14 - After pre-cleaning, are items appropriately wrapped or packaged for sterilization according to the manufacturer's IFU?
- ☐ Yes
- ☐ No
- ☐ Unsure

15 - Is a chemical indicator (process indicator) correctly placed in the instrument packs of every load?
- ☐ Yes
- ☐ No
- ☐ Unsure

16 - Is a biological indicator used at least weekly for each sterilizer?
- ☐ Yes
- ☐ No
- ☐ Unsure

17 - Is a biological indicator included with every load containing implantable items?
- ☐ Yes
- ☐ No
- ☐ Unsure

18 - Does the facility maintain thorough documentation of all sterile processing activities in all areas where sterile processing occurs? (including clinics and satellite departments)
- ☐ Yes
- ☐ No
- ☐ Unsure

19 - Do logs for each sterilizer include results from every load that is run?
- ☐ Yes
- ☐ No
- ☐ Unsure

20 - Sterile packs are labeled with:
- ☐ The sterilizer used
- ☐ Cycle
- ☐ Load numbers

- ☐ Date of sterilization
- ☐ Expiration date
- ☐ Other

21 - Is the IPC program reviewing sterile processing documentation?
- ☐ Yes
- ☐ No
- ☐ Unsure

22 - After sterilization, are critical devices stored in a standardized manner to protect them from damage and contamination?
- ☐ Yes
- ☐ No
- ☐ Unsure

23 - Are sterile packages inspected for integrity prior to use?
- ☐ Yes
- ☐ No
- ☐ Unsure

24 - Does the facility's procedure scheduling allow sufficient time for all device reprocessing steps?
- ☐ Yes
- ☐ No
- ☐ Unsure

25 - Does the facility have an adequate supply of instruments for the volume of procedures?
- ☐ Yes
- ☐ No
- ☐ Unsure

Immediate-use Steam Sterilization

26 - Does the facility utilize immediate-use steam sterilization (IUSS)?
- ☐ Yes
- ☐ No
- ☐ Unsure

27 - Does the facility have a defined goal to track and decrease IUSS utilization?
- ☐ Yes
- ☐ No
- ☐ Unsure

28a - Is IUSS data shared with the Infection Control Committee or quality committee for review?
- ☐ Yes
- ☐ No
- ☐ Unsure

28b - What is the frequency of IUSS review at committee (either ICC or quality)?
- ☐ Monthly
- ☐ Quarterly

☐ Every 6 months
☐ Annually
☐ None
☐ Other

29 - Do IUSS protocols and procedures address indications and contraindications of IUSS at the facility?
☐ Yes
☐ No
☐ Unsure
☐ Not Applicable

30 - If IUSS is performed, all the following are met:
☐ Proper cleaning of device per IFU
☐ Proper inspection of device per IFU
☐ Proper arrangement of devices for sterilization
☐ Once clean, the item is placed within a container intended for immediate use
☐ The sterilizer cycle and parameters used are met in accordance with the manufacturer's IFU for the device, container, AND sterilizer
☐ The sterilizer function is monitored with indicators that are approved for the cycle being used
☐ The processed item is immediately transferred using aseptic technique from the sterilizer to the actual point of use, which is the sterile field in an ongoing procedure.
☐ None of the above
☐ Other

31 - If unused, items that have undergone IUSS are re-sterilized per the manufacturer's IFU for long-term storage
☐ Yes
☐ No
☐ Unsure

Single Use Devices

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

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

34 - 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

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

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

Reprocessing Failure

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

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

39a - Are investigations performed in reprocessing failure events?
☐ Yes
☐ No
☐ Unsure

39b - What is included in the reprocessing failure investigation?
☐ Reload to identify potential user error
☐ Quarantine loads until root cause is identified
☐ Sterilizer in question is removed from service
☐ Determine cause of failure (e.g., sterilizer malfunction, positive biological indicator, chemical indicator failure)
☐ Recall of all items back to the last Negative biological indicator
☐ Positive biological indicators are sent to microbiology for presumptive identification
☐ Consultation with the Infection Preventionist if a contaminated instrument was used on a patient
☐ Other

40 - 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

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

42a - Does the facility track all components and accessories of reprocessible devices that may be used on patients?
- ☐ Yes
- ☐ No
- ☐ Unsure

42b - What systems are in place to identify devices and accessories used on patients?
- ☐ Device numbers linked in electronic health record
- ☐ Device numbers written in paper chart
- ☐ Paper log in procedural areas
- ☐ Electronic record kept in device reprocessing (e.g., scan/ case cart system)
- ☐ No system for tracking exists
- ☐ Other

Device Procurement and Loan

43a - Does the facility have a formalized device procurement and purchasing process?
- ☐ Yes
- ☐ No
- ☐ Unsure

43b - Is the IPC program consulted when new devices or products are introduced?
- ☐ Always
- ☐ Often
- ☐ Rarely
- ☐ Never

43c - Is the sterile processing leadership consulted when new devices or products are introduced?
- ☐ Always
- ☐ Often
- ☐ Rarely
- ☐ Never

44a - Does the facility have a formalized process for loaned or borrowed instrumentation?
- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Not Applicable

44b - What is included in the program for loaned or borrowed devices and instruments?
- ☐ Required time for cleaning prior to procedure
- ☐ Location to receive borrowed devices or instruments

- ☐ Borrowed device logs and inventory process
- ☐ Manufacturer IFU prior to receiving loaned items
- ☐ Transport process of loaned instrumentation to the point of use
- ☐ Return process to sterile processing from point of use
- ☐ Return process from sterile processing to lender
- ☐ Documentation of loaned equipment
- ☐ None of the above
- ☐ Other

44c - Do all borrowed or loaded devices or instrumentation undergo necessary disinfection and sterilization per the manufacturer's IFU prior to use at the facility?

- ☐ Yes
- ☐ No
- ☐ Unsure

45a - If devices are not received with enough time for a full sterilization or disinfection cycle, is the procedure allowed to continue with a shortened sterilization or disinfection cycle?

- ☐ Yes
- ☐ No
- ☐ Unsure

45b - Is this only in emergent, life-threatening scenarios where no alternative exists?

- ☐ Yes
- ☐ No
- ☐ Unsure

Education & Training

46 - Does the facility have a competency-based training program for device reprocessing?

- ☐ Yes
- ☐ No
- ☐ Unsure

47a - Who receives 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

47b - What is included in critical device reprocessing training and education?

- ☐ Spaulding classification
- ☐ PPE for critical device reprocessing
- ☐ 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
- ☐ Sterilization
- ☐ Packaging
- ☐ Storage
- ☐ Documentation
- ☐ Quality control
- ☐ Maintenance
- ☐ None of the above
- ☐ Other

48 - 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

49 - Are any staff certified in Sterile Processing at the facility? If so, what certification do they hold?

- ☐ International Association of Healthcare Central Service Material Management (IAHSM)
- ☐ Certified Sterile Processing and Distribution Tech (CSPDT)
- ☐ National Commission for Certifying Agencies (NCCA)
- ☐ No staff are certified
- ☐ Other

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

- ☐ Yes
- ☐ No
- ☐ Unsure

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

- ☐ Yes
- ☐ No
- ☐ Unsure

Audit & Feedback

52 - Does the facility audit adherence to reprocessing procedures?

- ☐ Yes
- ☐ No
- ☐ Unsure

53 - How are critical device audits performed?

- ☐ Direct observation following checklist/ IFU
- ☐ ATP tracking

- ☐ Blacklight
- ☐ Culture-based methods
- ☐ IUSS logs
- ☐ Sterilizer log review
- ☐ None of the above
- ☐ Other

54a - Are device reprocessing audits performed in all areas where device reprocessing occurs?

- ☐ Yes- all areas
- ☐ No- not all areas
- ☐ Unsure

54b - Which areas do not consistently perform device reprocessing audits?

- ☐ Emergency Department
- ☐ Labor & Delivery
- ☐ Women's services
- ☐ Respiratory Therapy
- ☐ Radiology
- ☐ Dialysis
- ☐ Physical/ Occupational Therapy
- ☐ Child-life, areas with toy cleaning
- ☐ ENT clinics
- ☐ Dermatology clinics
- ☐ Pulmonary clinics
- ☐ Med spas
- ☐ Other

55a - Does the facility provide feedback from the audits to healthcare personnel?

- ☐ Yes
- ☐ No
- ☐ Unsure

55b - Do auditor(s) provide immediate real-time feedback to healthcare personnel in the moment?

- ☐ Yes
- ☐ No
- ☐ Unsure

56 - Does the IP perform independent audits in the Sterile Processing Department?

- ☐ Yes
- ☐ No
- ☐ Unsure

Environment of Care

57 - Does the facility monitor the HVAC settings of areas where sterile processing occurs?

- ☐ Yes
- ☐ No
- ☐ Unsure

58 - Does the facility monitor the steam settings of areas where sterile processing occurs?
- ☐ Yes
- ☐ No
- ☐ Unsure

59a - Does the Water Management team evaluate and monitor the steam and water quality for sterile processing areas?
- ☐ Yes
- ☐ No
- ☐ Unsure

59b - Does the IP routinely receive SPD water and steam monitoring reports?
- ☐ Yes
- ☐ No
- ☐ Unsure

60 - Are backup procedures in place if parameters specific to sterile processing areas are not met? (e.g., air exchanges, humidity, water, or temperature parameters)
- ☐ Yes
- ☐ No
- ☐ Unsure

61 - Is there a functional and clear separation between the clean area and the decontamination area?
- ☐ Yes
- ☐ No
- ☐ Unsure

62 - Is there a clear, separate work area for packaging, sterilization and storage within the sterile processing department?
- ☐ Yes
- ☐ No
- ☐ Unsure

63 - Are there clear, restricted areas within sterile processing to minimize traffic within the area?
- ☐ Yes
- ☐ No
- ☐ Unsure

64 - 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

65a - What is the air pressure differential of the SOILED HOLDING ROOM area within Sterile Processing?
- ☐ Negative Pressure
- ☐ Positive Pressure
- ☐ Neutral Pressure
- ☐ N/A

65b - What is the air pressure differential of the DECONTAMINATION area within Sterile Processing?

- ☐ Negative Pressure
- ☐ Positive Pressure
- ☐ Neutral Pressure
- ☐ N/A

65c - What is the air pressure differential of the ASSEMBLY/STERILIZATION area within Sterile Processing?

- ☐ Negative Pressure
- ☐ Positive Pressure
- ☐ Neutral Pressure
- ☐ N/A

65c - What is the air pressure differential of the STERILIZER EQUIPMENT ROOM within Sterile Processing?

- ☐ Negative Pressure
- ☐ Positive Pressure
- ☐ Neutral Pressure
- ☐ N/A

65d - What is the air pressure differential of the STERILE STORAGE area within Sterile Processing?

- ☐ Negative Pressure
- ☐ Positive Pressure
- ☐ Neutral Pressure
- ☐ N/A

Answer Key

Policy & Procedure

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

[X] Yes - *Preferred*
[ ] No
[ ] Unsure

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

[X] Spaulding classification **- *Preferred***
[X] Critical device disinfection process preparation (e.g., pre-cleaning, manual/mechanical cleaning, chemical preparation, etc.) **- *Preferred***
[X] Required PPE for sterilization **- *Preferred***
[X] Approved solutions and settings for sterilization **- *Preferred***
[X] Visual inspection **- *Preferred***
[X] Sterilizer specific monitoring requirements (e.g., temperature, humidity, documentation, indicators, etc.) **- *Preferred***
[X] Sterilization **- *Preferred***
[X] Storage **- *Preferred***
[X] Device transport **- *Preferred***
[X] Device maintenance protocols **- *Preferred***
[X] Single-use and multi-use accessories **- *Preferred***
[X] Device/ instrument purchasing requirements **- *Preferred***
[X] Borrowed instrumentation or devices **- *Preferred Optional***
[X] Device reprocessing failure protocol (e.g., positive indicators, etc.) **- *Preferred***
[X] Special procedures: Creutzfeldt-Jakob disease (CJD), Immediate-use steam sterilization (IUSS), etc. **- *Preferred Optional***
[ ] None of the above

General Practice

2 - Sterile processing is performed: **(Not Scored – Informational Only)**

[ ] Onsite (centralized or decentralized)
[ ] Off-site by hired vendor
[ ] Combination of onsite and offsite
[ ] None. Sterile processing is not required at the facility

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

[X] Yes - *Preferred*
[ ] No
[ ] Unsure

4 - Are items pre-cleaning and moistened prior to off-site transport?

[X] Yes - *Preferred*
[ ] No
[ ] Unsure

5 - How are items prepared for off-site transport? **(Select <u>all</u> preferred options)**
[X] Pre-cleaned per manufacturer IFU ***- Preferred***
[X] Placed in puncture-resistant and lockable biohazard container ***- Preferred***
[X] Manual wiping of device ***- Preferred***
[X] Items kept wet with enzymatic or transport gel ***- Preferred***
[ ] Other

6 - Is the IPC program aware of all types of sterilizers in use at the facility?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

7 - Are manufacturer IFUs available to staff at the point of use to ensure manufacturer's instructions are followed for sterile processing?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

8 - Are critical items sterilized prior to each use?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

9 - Critical items labeled for single-use are: **(Select at least one preferred option)**
[X] Discarded after each use ***- Preferred***
[X] Reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor AND is cleared by the FDA to reprocess the specific device in question ***- Preferred***
[ ] Reprocessed at facility without FDA authorization
[ ] Other

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

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

12 - Do instruments with lumens, undergo pre-cleaning of all channels using separate cleaning brushes approved by the manufacturer?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

13 - Is the enzymatic or detergent used for cleaning discarded according to the manufacturer's IFU (typically after each use)?
[X] Yes - *Preferred*

[ ] No

14 - After pre-cleaning, are items appropriately wrapped or packaged for sterilization according to the manufacturer's IFU?
[X] Yes - *Preferred*
[ ] No

15 - Is a chemical indicator (process indicator) correctly placed in the instrument packs of every load?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

16 - Is a biological indicator used at least weekly for each sterilizer?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

17 - Is a biological indicator included with every load containing implantable items?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

18 - Does the facility maintain thorough documentation of all sterile processing activities in all areas where sterile processing occurs? (including clinics and satellite departments)
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

19 - Do logs for each sterilizer include results from every load that is run?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

20 - Sterile packs are labeled with: **(Select <u>all</u> preferred options)**
[X] The sterilizer used **- *Preferred***
[X] Cycle **- *Preferred***
[X] Load numbers **- *Preferred***
[X] Date of sterilization **- *Preferred***
[X] Expiration date **- *Preferred***
[ ] Other

21 - Is the IPC program reviewing sterile processing documentation?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

22 - After sterilization, are critical devices stored in a standardized manner to protect them from damage and contamination?
[X] Yes - *Preferred*

[ ] No
[ ] Unsure

23 - Are sterile packages inspected for integrity prior to use?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

24 - Does the facility's procedure scheduling allow sufficient time for all device reprocessing steps?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

25 - Does the facility have an adequate supply of instruments for the volume of procedures?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

Immediate-use Steam Sterilization

26 - Does the facility utilize immediate-use steam sterilization (IUSS)? **(Not Scored – Informational Only)**
[ ] Yes
[ ] No
[ ] Unsure

27 - Does the facility have a defined goal to track and decrease IUSS utilization?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

28a - Is IUSS data shared with the Infection Control Committee or quality committee for review?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

28b - What is the frequency of IUSS review at committee (either ICC or quality)? **(Select at least one preferred option)**
[X] Monthly **- *Preferred***
[X] Quarterly **- *Preferred***
[X] Every 6 months
[X] Annually
[ ] None
[ ] Other

29 - Do IUSS protocols and procedures address indications and contraindications of IUSS at the facility?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

[ ] Not Applicable - Not Scored

30 - If IUSS is performed, all the following are met: **(Select <u>all</u> preferred options)**
[X] Proper cleaning of device per IFU **- *Preferred***
[X] Proper inspection of device per IFU **- *Preferred***
[X] Proper arrangement of devices for sterilization **- *Preferred***
[X] Once clean, the item is placed within a container intended for immediate use **- *Preferred***
[X] The sterilizer cycle and parameters used are met in accordance with the manufacturer's IFU for the device, container, AND sterilizer **- *Preferred***
[X] The sterilizer function is monitored with indicators that are approved for the cycle being used **- *Preferred***
[X] The processed item is immediately transferred using aseptic technique from the sterilizer to the actual point of use, which is the sterile field in an ongoing procedure. **- *Preferred***
[ ] None of the above
[ ] Other

31 - If unused, items that have undergone IUSS are re-sterilized per the manufacturer's IFU for long-term storage
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

Single Use Devices

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

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

34 - 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

35 - Does the hospital 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

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

Reprocessing Failure

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

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

39a - Are investigations performed in reprocessing failure events?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

39b - What is included in the reprocessing failure investigation? **(Select <u>all</u> preferred options)**
[X] Reload to identify potential user error **- *Preferred***
[X] Quarantine loads until root cause is identified **- *Preferred***
[X] Sterilizer in question is removed from service **- *Preferred***
[X] Determine cause of failure (e.g., sterilizer malfunction, positive biological indicator, chemical indicator failure) **- *Preferred***
[X] Recall of all items back to the last Negative biological indicator **- *Preferred***
[X] Positive biological indicators are sent to microbiology for presumptive identification **- *Preferred***
[X] Consultation with the Infection Preventionist if a contaminated instrument was used on a patient **- *Preferred***
[ ] Other

40 - 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

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

42a - Does the facility track all components and accessories of reprocessible devices that may be used on patients?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

42b - What systems are in place to identify devices and accessories used on patients? **(Select at least one preferred option)**
[X] Device numbers linked in electronic health record **- *Preferred***
[X] Device numbers written in paper chart **- *Preferred***
[X] Paper log in procedural areas **- *Preferred***
[X] Electronic record kept in device reprocessing (e.g., scan/ case cart system) **- *Preferred***
[ ] No system for tracking exists
[ ] Other

Device Procurement and Loan

43a - Does the facility have a formalized device procurement and purchasing process?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

43b - Is the IPC program consulted when new devices or products are introduced?
[X] Always **- *Preferred***
[ ] Often **- *Preferred***
[ ] Rarely
[ ] Never

43c - Is the sterile processing leadership consulted when new devices or products are introduced?
[X] Always **- *Preferred***
[ ] Often **- *Preferred***
[ ] Rarely
[ ] Never

44a - Does the facility have a formalized process for loaned or borrowed instrumentation?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure
[ ] Not Applicable - Not Scored

44b - What is included in the program for loaned or borrowed devices and instruments? **(Select <u>all</u> preferred options)**
[X] Required time for cleaning prior to procedure **- *Preferred***
[X] Location to receive borrowed devices or instruments **- *Preferred***
[X] Borrowed device logs and inventory process **- *Preferred***
[X] Manufacturer IFU prior to receiving loaned items **- *Preferred***
[X] Transport process of loaned instrumentation to the point of use **- *Preferred***
[X] Return process to sterile processing from point of use **- *Preferred***

[X] Return process from sterile processing to lender **- *Preferred***
[X] Documentation of loaned equipment **- *Preferred***
[ ] None of the above
[ ] Other

44c - Do all borrowed or loaded devices or instrumentation undergo necessary disinfection and sterilization per the manufacturer's IFU prior to use at the facility?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

45a - If devices are not received with enough time for a full sterilization or disinfection cycle, is the procedure allowed to continue with a shortened sterilization or disinfection cycle?
[ ] Yes - Not Scored
[X] No - *Preferred*
[ ] Unsure

45b - Is this only in emergent, life-threatening scenarios where no alternative exists?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

Education & Training

46 - Does the facility have a competency-based training program for device reprocessing?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

47a - Who receives critical device reprocessing training and education as it pertains to their job role?
(Select <u>all</u> 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

47b - What is included in critical device reprocessing training and education? **(Select <u>all</u> preferred options)**
[X] Spaulding classification **- *Preferred***
[X] PPE for critical device reprocessing **- *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] Sterilization **- *Preferred***
[X] Packaging **- *Preferred***
[X] Storage **- *Preferred***
[X] Documentation **- *Preferred***
[X] Quality control **- *Preferred***
[X] Maintenance **- *Preferred***
[ ] None of the above
[ ] Other

48 - What frequency is device reprocessing training and education provided? **(Select <u>all</u> 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

49 - Are any staff certified in Sterile Processing at the facility? If so, what certification do they hold? **(Not Scored – Informational Only)**
[ ] International Association of Healthcare Central Service Material Management (IAHSM)
[ ] Certified Sterile Processing and Distribution Tech (CSPDT)
[ ] National Commission for Certifying Agencies (NCCA)
[ ] No staff are certified - Not Scored
[ ] Other - Not Scored

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

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

Audit & Feedback

52 - Does the facility audit adherence to reprocessing procedures?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

53 - How are critical device audits performed? **(Select <u>all</u> 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] IUSS logs **- *Preferred***
[X] Sterilizer log review **- *Preferred***
[ ] None of the above
[ ] Other

54a - Are device reprocessing audits performed in all areas where device reprocessing occurs?
[X] Yes- all areas - *Preferred*
[ ] No- not all areas
[ ] Unsure

54b - Which areas do not consistently perform device reprocessing audits? **(Not Scored – Informational Only)**
[ ] Emergency Department
[ ] Labor & Delivery
[ ] Women's services
[ ] Respiratory Therapy
[ ] Radiology
[ ] Dialysis
[ ] Physical/ Occupational Therapy
[ ] Child-life, areas with toy cleaning
[ ] ENT clinics
[ ] Dermatology clinics
[ ] Pulmonary clinics
[ ] Med spas
[ ] Other

55a - Does the facility provide feedback from the audits to healthcare personnel?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

55b - Do auditor(s) provide immediate real-time feedback to healthcare personnel in the moment?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

56 - Does the IP perform independent audits in the Sterile Processing Department?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

Environment of Care

57 - Does the facility monitor the HVAC settings of areas where sterile processing occurs?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

58 - Does the facility monitor the steam settings of areas where sterile processing occurs?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

59a - Does the Water Management team evaluate and monitor the steam and water quality for sterile processing areas?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

59b - Does the IP routinely receive SPD water and steam monitoring reports?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

60 - Are backup procedures in place if parameters specific to sterile processing areas are not met? (e.g., air exchanges, humidity, water, or temperature parameters)
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

61 - Is there a functional and clear separation between the clean area and decontamination area?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

62 - Is there a clear, separate work area for packaging, sterilization and storage within the sterile processing department?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

63 - Are there clear, restricted areas within sterile processing to minimize traffic within the area?
[X] Yes - *Preferred*
[ ] No
[ ] Unsure

64 - 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

65a - What is the air pressure differential of the SOILED HOLDING ROOM area within Sterile Processing?
[X] Negative Pressure - *Preferred*
[ ] Positive Pressure
[ ] Neutral Pressure
[ ] N/A - Not Scored

65b - What is the air pressure differential of the DECONTAMINATION area within Sterile Processing?

[X] Negative Pressure - *Preferred*
[ ] Positive Pressure
[ ] Neutral Pressure
[ ] N/A - Not Scored

65c - What is the air pressure differential of the ASSEMBLY/STERILIZATION area within Sterile Processing?

[ ] Negative Pressure
[X] Positive Pressure **- *Preferred***
[ ] Neutral Pressure
[ ] N/A - Not Scored

65c - What is the air pressure differential of the STERILIZER EQUIPMENT ROOM within Sterile Processing?

[X] Negative Pressure - *Preferred*
[ ] Positive Pressure
[ ] Neutral Pressure
[ ] N/A - Not Scored

65d - What is the air pressure differential of the STERILE STORAGE area within Sterile Processing?

[ ] Negative Pressure
[X] Positive Pressure - *Preferred*
[ ] Neutral Pressure
[ ] N/A - Not Scored

Guidance

Policy & 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. (2020). 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 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

Immediate-use Steam Sterilization

Core Element Description: Assessment of immediate-use steam sterilization (IUSS) utilization and practices at the facility.

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

The Joint Commission. (2017). What are the important considerations associated with immediate-use steam sterilization? https://www.jointcommission.org/en-us/knowledge-library/support-center/standards-interpretation/standards-faqs/000002122

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

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. (2024, June). 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://www.store.aami.org/s/store#/store/browse/detail/a152E00000A7DU5QAN

Device Procurement and Loan

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

Free Access: Resources

Centers for Disease Control and Prevention. (2024) Infection Prevention and control assessment tool for acute care hospitals. https://www.cdc.gov/healthcare-associated-

infections/php/toolkit/icar.html?CDC_AAref_Val=https://www.cdc.gov/hai/prevent/infection-control-assessment-tools.html

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. (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. (2026). 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. (2026). 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. (2026). 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. (2026). 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. (2026). 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://www.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://www.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