

(Insert Facility Name)
Reprocessing Staff Competency

This is a template and is not all inclusive. Facilities should individualize according to internal policies.

Employee Name:							
Self-Assessment Key	Instruction Method			Validation Method			
0 - No Experience 1 - Limited competency/proficiency 2 - Acceptable competency/proficiency 3 - Competent/Proficient (has independently performed during the past year)	P - Protocol/Policy Procedure E - Education S - Self Learning Assignment CP - Clinical Practice D - Demonstration			O - Observation RT - Return Demonstration T - Test VR - Verbal Review C - Certificate			
Reprocessing Staff	Self - Assess	Instruction	Date	Validation Method	Date/Initials	Date/Initials	Date/initials
Foundational Knowledge and Documentation							
Staff demonstrates knowledge of the location and use of manufacturer's instructions for the equipment being reprocessed.							
Staff demonstrates knowledge of the rationale for the essential steps of reprocessing (e.g., pre-clean, cleaning, disinfection/sterilization).							
Staff demonstrates competence in reprocessing all specific types/models of devices assigned to them.							
Environmental and Occupational Safety (General Reprocessing Area)							
Work areas maintain a clear separation and traffic flow pattern between soiled and clean areas.							
Staff have ready access to and correctly don appropriate personal protective equipment for the task, including gloves, cover gowns, and eye/face protection.							
An eyewash station is readily available (within a 10 second travel distance from chemicals) and is functioning.							
Safety Data Sheets for chemicals used in the area are readily available.							
Spill kits are readily available in the reprocessing area.							
Staff accesses a handwashing sink separate from the device cleaning sink(s).							
Pre-Cleaning and Manual Cleaning Steps (Dirty Area)							
Pre-cleaning is performed at the point of use as soon as practical after the device is used, to prevent soiled materials from drying onto the instruments.							

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Reprocessing Staff	Self - Assess	Instruction	Date	Validation Method	Date/Initials	Date/Initials	Date/initials
Contaminated instruments are transported to the reprocessing area in a closed, leakproof, puncture-resistant container labeled with a biohazard legend.							
Staff disassembles multi-part instruments and opens hinged instruments prior to cleaning.							
Staff uses water and enzymatic or detergent cleaners compatible with the device/instrument materials, following manufacturer dilution and temperature requirements.							
Staff meticulously cleans all surfaces, internal channels, and ports by flushing and brushing until no debris appears on the brush.							
Staff discards enzymatic cleaners/detergents after each use.							
Staff discards or thoroughly cleans and disinfects/sterilizes reusable cleaning items (e.g., brushes, cloths) after each use.							
Staff visually inspects the device for residual soil or damage after cleaning and before high-level disinfection/sterilization.							
High-level Disinfection (HLD) Specifics							
If observing flexible endoscope reprocessing, staff performs leak testing.							
Staff uses an FDA-cleared liquid sterilant/high-level disinfectant compatible with the device.							
Staff routinely tests the disinfectant product using the appropriate chemical indicator (test strip) each day of use (or more frequently) to ensure the minimum effective concentration is met.							
Staff documents the results of test strip quality control and potency testing.							
Staff ensures the disinfectant product is within the recommended manufacturer's "use by" date.							

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Reprocessing Staff	Self - Assess	Instruction	Date	Validation Method	Date/Initials	Date/Initials	Date/initials
Staff completely immerses the device to the HLD for the correct contact time and temperature specified by the manufacturer.							
After HLD, staff performs thorough rinsing according to manufacturer's instructions.							
After rinsing, staff use forced air to facilitate drying process per manufacturer's instructions.							
Sterilization Specifics							
Instruments are correctly wrapped/packaged for the sterilization process, utilizing FDA 510[k]-cleared packaging materials, placed loosely to allow sterilant penetration.							
A chemical indicator is correctly placed inside the instrument packs in every load.							
If a dynamic-air removal sterilizer (e.g., prevacuum steam sterilizer) is used, a Bowie-Dick test is performed daily before the first process load.							
A biological indicator (BI), intended for the specific sterilizer type/cycle, is used at least weekly, and used with every load containing implantable items.							
Final Steps, Storage, and Documentation							
Staff inspects sterile packages for integrity (e.g., torn, wet, punctured) before storage or use, and reprocess compromised packages.							
HLD/Sterilized devices are stored in a manner that protects them from damage and contamination (e.g., endoscopes hung vertically to facilitate drying).							
Staff maintains a log for all reprocessed items.							

Sterilization Practices Observation Tool

Observer: _____

Date: _____

Observation Area:	Observation:	Comments/Corrective Action:
Is the sterile reprocessing area divided into distinct areas: Decontamination, Assembly/Packaging, Sterilization, and Sterile Storage?	☐ Yes ☐ No	
Are the signs detailing reprocessing steps, the manufacturer's instructions for each item reprocessed, and the relevant policies and procedures all readily visible or available in the area?	☐ Yes ☐ No	
Are spill kits readily available?	☐ Yes ☐ No	
Are safety data sheets available for the chemicals used in the area?	☐ Yes ☐ No	
Is an eyewash station available within a 10 second travel distance from chemicals being used?	☐ Yes ☐ No	
Is weekly eyewash station maintenance documented?	☐ Yes ☐ No	
Is there a handwashing sink that is separate from the reprocessing sink(s)?	☐ Yes ☐ No	
Are personnel wearing appropriate personal protective equipment?	☐ Yes ☐ No	
Are soiled instruments precleaned at the point of use?	☐ Yes ☐ No	
Are instruments transported to the reprocessing area in the appropriate biohazard container?	☐ Yes ☐ No	
Are instruments cleaned either manually or mechanically?	☐ Yes ☐ No	
Are instruments visually inspected after cleaning?	☐ Yes ☐ No	
Are cleaning products discarded according to manufacturer's instructions?	☐ Yes ☐ No	
Are cleaning brushes single-use and discarded?	☐ Yes ☐ No	
If cleaning brushes are reusable, are they cleaned and high-level disinfected or sterilized according to manufacturer's instructions?	☐ Yes ☐ No	
Are instruments wrapped/packaged using compatible materials for the sterilization method?	☐ Yes ☐ No	
Are internal or external chemical indicators monitored every load?	☐ Yes ☐ No	
Are biological indicators monitored weekly and with every load containing implantable items?	☐ Yes ☐ No	

Sterilization Practices Observation Tool

Is an air-removal (Bowie-Dick) test performed daily in an empty chamber for all dynamic-air-removal (prevacuum) steam sterilizers?	☐ Yes ☐ No	
Are items loaded into the sterilizer according to the manufacturer's instructions?	☐ Yes ☐ No	
Are the following recorded for each sterilization cycle: sterilizer/cycle type, load ID, load contents, time and temperature, operator initials, and mechanical, chemical, and biological monitoring results?	☐ Yes ☐ No	
Are sterile instruments stored in a manner to protect them from damage and contamination?	☐ Yes ☐ No	
Are sterile packages assessed for integrity issues prior to use?	☐ Yes ☐ No	
Are compromised sterile packages returned for reprocessing?	☐ Yes ☐ No	

To Calculate Rate: $(A/B) \times 100 = \text{Percentage} _____\%$

(A) Total Number of answers Yes: $_____\$

(B) Total Number of Observations: $_____\$

High-level Disinfection (HLD) Practices Observation Tool

Observer: _____ Date: _____

Observation Area:	Observation:	Comments/Corrective Action:
Is the reprocessing area separate from the procedure area?	☐ Yes ☐ No	
Is the reprocessing area set-up to ensure a "one-way" workflow separating dirty from clean?	☐ Yes ☐ No	
Are the signs detailing reprocessing steps, the manufacturer's instructions for each item reprocessed, and the relevant policies and procedures all readily visible or available in the area?	☐ Yes ☐ No	
Are spill kits readily available?	☐ Yes ☐ No	
Are safety data sheets available for the chemicals used in the area?	☐ Yes ☐ No	
Is an eyewash station available within a 10 second travel distance from chemicals being used?	☐ Yes ☐ No	
Is weekly eyewash station maintenance documented?	☐ Yes ☐ No	
Is there a handwashing sink that is separate from the reprocessing sink(s)?	☐ Yes ☐ No	
Are personnel in the reprocessing area wearing appropriate personal protective equipment?	☐ Yes ☐ No	
Are soiled instruments precleaned at the point of use?	☐ Yes ☐ No	
Are instruments transported to the reprocessing area in the appropriate biohazard container?	☐ Yes ☐ No	
Are instruments cleaned either manually or mechanically?	☐ Yes ☐ No	
Are instruments visually inspected after cleaning?	☐ Yes ☐ No	
Are cleaning products discarded according to manufacturer's instructions?	☐ Yes ☐ No	
Are cleaning brushes single-use and discarded?	☐ Yes ☐ No	
If cleaning brushes are reusable, are they cleaned and high-level disinfected or sterilized according to manufacturer's instructions?	☐ Yes ☐ No	
Is leak testing conducted on endoscopes to detect damage?	☐ Yes ☐ No	
Is the high-level disinfectant in use FDA-cleared?	☐ Yes ☐ No	

High-level Disinfection (HLD) Practices Observation Tool

Is the HLD solution within the manufacturer's instructions specified use-life (e.g., 14-30 days after activation)?	☐ Yes ☐ No	
Is the minimum effective concentration (MEC) of the solution tested and documented per the manufacturer's instructions using the correct chemical indicator strips?	☐ Yes ☐ No	
Is the solution discarded if the MEC test fails or the use-life has expired?	☐ Yes ☐ No	
Are the chemical indicator strips, used for MEC, labeled with open and use-by dates?	☐ Yes ☐ No	
Is the temperature of the HLD solution monitored to ensure it meets the parameters per manufacturer's instructions?	☐ Yes ☐ No	
Are HLD immersion baths (if applicable) kept covered with tight-fitting lids to minimize chemical vapors and prevent contamination?	☐ Yes ☐ No	
Are cleaned instruments fully and completely immersed in the HLD solution?	☐ Yes ☐ No	
Is a timer used to ensure the instruments are immersed for the full contact time per manufacturer's instructions?	☐ Yes ☐ No	
If using an automated reprocessor, are proper connectors used to assure that channels and lumens are appropriately disinfected per manufacturer's instructions?	☐ Yes ☐ No	
After disinfection, are instruments rinsed per manufacturer's instructions?	☐ Yes ☐ No	
After rinsing, are instrument channels dried using forced air per manufacturer's instructions?	☐ Yes ☐ No	
Are disinfected items stored in a manner that protects them from contamination or damage?	☐ Yes ☐ No	
Are disinfected items labeled with dates?	☐ Yes ☐ No	
Are the following documented for each HLD cycle: reprocessing method and products, reprocessed item, patient identifiers, manual cleaning start and end times, preventive maintenance and repairs, and reprocessing staff?	☐ Yes ☐ No	

To Calculate Rate: $(A/B) \times 100 = \text{Percentage}$ _____%

(A) Total Number of answers Yes: _____

(B) Total Number of Observations: _____

Learning Activity:

Identifying Critical and Semicritical Equipment

This learning activity is designed to help distinguish between critical and semicritical medical equipment, based on the fundamental Spaulding Classification system, which categorizes patient care items according to the risk of infection involved with their use.

Objective

For each piece of representative equipment:

1. **Classify** it as **Critical (C)** or **Semicritical (SC)**.
2. **Identify** the minimum required level of reprocessing (Sterilization (**Sterile**) or High-level Disinfection (**HLD**)).

Background: The Spaulding Classification System

Category:	Definition:	Minimum Required Reprocessing:
Critical Items (C)	Objects that enter sterile tissue or the vascular system .	Must be Sterile .
Semicritical Items (SC)	Objects that contact mucous membranes or nonintact skin .	At least HLD .

Activity: Equipment Identification

Below are descriptions of patient-care devices. Determine the classification and required reprocessing level for each.

Equipment Description:	Classification:	Minimum Required Reprocessing:
A: Flexible Gastrointestinal Endoscope (Used for colonoscopy)	☐ SC ☐ C	☐ HLD ☐ Sterile
B: Surgical Biopsy Forceps (Accessory inserted through an endoscope to break the mucosal barrier)	☐ SC ☐ C	☐ HLD ☐ Sterile
C: Laryngoscope Blade (Used for airway management, contacts mucous membranes)	☐ SC ☐ C	☐ HLD ☐ Sterile
D: Endocavitary Probe (Used for vaginal or rectal scanning)	☐ SC ☐ C	☐ HLD ☐ Sterile
E: Dental Extraction Forcep (Used to penetrate soft tissue/bone)	☐ SC ☐ C	☐ HLD ☐ Sterile

Learning Activity:

Identifying Critical and Semicritical Equipment

Answer Key

Activity: Equipment Identification

Below are descriptions of patient-care devices. Determine the classification and required reprocessing level for each.

Equipment Description:	Classification:	Minimum Required Reprocessing:
A: Flexible Gastrointestinal Endoscope (Used for colonoscopy)	☒ SC ☐ C	☒ HLD ☐ Sterile
B: Surgical Biopsy Forceps (Accessory inserted through an endoscope to break the mucosal barrier)	☐ SC ☒ C	☐ HLD ☒ Sterile
C: Laryngoscope Blade (Used for airway management, contacts mucous membranes)	☒ SC ☐ C	☒ HLD ☐ Sterile
D: Endocavitary Probe (Used for vaginal or rectal scanning)	☒ SC ☐ C	☒ HLD ☐ Sterile
E: Dental Extraction Forcep (Used to penetrate soft tissue/bone)	☐ SC ☒ C	☐ HLD ☒ Sterile

Disinfection and Sterilization

Test Your Knowledge

This eight-question true/false quiz is based on the procedures and guidelines found in the U.S. Centers for Disease Control and Prevention Disinfection and Sterilization guideline.

Question:	True:	False:
1. Medical devices must be cleaned as soon as practical after use (e.g., at the point of use) because dried materials on the instruments make the removal process more difficult and reduce the effectiveness of subsequent disinfection or sterilization.	☐ True	☐ False
2. Critical items, such as surgical instruments that enter sterile tissue or the vascular system, require at least high-level disinfection, but sterilization is considered optional.	☐ True	☐ False
3. Semicritical items, such as flexible endoscopes that contact mucous membranes or non-intact skin, must undergo sterilization between uses.	☐ True	☐ False
4. Every sterilization load containing implantable items must be monitored using a biological indicator.	☐ True	☐ False
5. When reprocessing devices, personnel must wear appropriate personal protective equipment primarily to protect against infectious agents, but not against chemical exposure.	☐ True	☐ False
6. Enzymatic cleaners or detergents used for the manual cleaning of endoscopes may be reused repeatedly throughout a shift, as long as the solution is visibly clean.	☐ True	☐ False
7. Immediate-use steam sterilization should not be used merely for convenience, as an alternative to purchasing additional instrument sets, or to save time.	☐ True	☐ False
8. The Bowie-Dick test must be performed daily in an empty prevacuum steam sterilizer to ensure adequate air removal before the first processed load of the day.	☐ True	☐ False

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8. The Bowie-Dick test must be performed daily in an empty prevacuum steam sterilizer to ensure adequate air removal before the first processed load of the day.	☒ True	☐ False

Disinfection and Sterilization

Test Your Knowledge

This vocabulary quiz is based on the U.S. Centers for Disease Control and Prevention Disinfection and Sterilization Guideline.

Definition:	Answer:	Vocabulary Word:
1. A process that destroys or eliminates all forms of microbial life.		a. Disinfection
2. A process that eliminates many or all pathogenic microorganisms.		b. Intermediate-level Disinfection
3. A process that kills all microorganisms, with the exception of large numbers of bacterial spores.		c. Sterilization
4. A process that destroys mycobacteria, vegetative bacteria, most viruses, and most fungi, but does not necessarily kill bacterial spores.		d. Cleaning
5. A process that can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time.		e. Low-level Disinfection
6. This essential first step involves the removal of visible soil from objects and surfaces. It is typically accomplished manually or mechanically using water with detergents or enzymatic products.		f. High-level Disinfection

Name: _____

Date: _____

Score ___/6 x 100= ___%

Disinfection and Sterilization
Test Your Knowledge
Answer Key

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2. A process that eliminates many or all pathogenic microorganisms.	A	b. Intermediate-Level Disinfection
3. A process that kills all microorganisms, with the exception of large numbers of bacterial spores.	F	c. Sterilization
4. A process that destroys mycobacteria, vegetative bacteria, most viruses, and most fungi, but does not necessarily kill bacterial spores.	B	d. Cleaning
5. A process that can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time.	E	e. Low-Level Disinfection
6. This essential first step involves the removal of visible soil from objects and surfaces. It is typically accomplished manually or mechanically using water with detergents or enzymatic products.	D	f. High-Level Disinfection