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High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices

I. Description

This policy is to guide UNC Medical Center health care personnel (HCP) with the following reprocessing criteria/standards:

- Manual cleaning, decontamination, high-level disinfection (HLD) for semi-critical items
- HLD monitoring and quality assurance
- HLD documentation
- Strategies to reduce the risk for transmission of infectious disease associated with reprocessing reusable semi-critical devices

This policy addresses standards and accepted practices for semi-critical devices and instruments only. Non-critical and critical devices and instruments are not addressed in this policy. Please see the Infection Prevention policies: Sterilization of Reusable Patient Care Items and Environmental Services.

This policy does not address reprocessing of flexible endoscopes. For policy addressing ALL flexible endoscopes, please see the Infection Prevention policy: Endoscope.

II. Rationale

HLD is the required reprocessing procedure to render many reusable semi-critical items safe for all patients and to reduce the risk of cross-transmission. This policy guides the practices of UNC Medical Center HCP with HLD responsibilities and conveys strategies to reduce or eliminate the risk of transmission of infectious disease associated with reprocessing semi-critical items.

III. Policy

A. Definition

Term	Definition
Asepsis	The absence of disease-producing microorganisms.
Aseptic technique	Practices designed to render and maintain objects and areas maximally free from microorganisms.

Term	Definition
Bioburden	Population of viable microorganisms on or in an item.
Clean technique	Practices that reduce the numbers of microorganisms or prevent or reduce transmission from one person (or place) to another,
Cleaning	*Cleaning* is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.
Competent	Qualified or having adequate ability.
Competency	Documentation of qualified or adequate ability to perform a task.
Critical device	Per Spaulding classification scheme, devices that enter normally sterile tissue.
Decontamination	Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.
Disinfectant	An agent that destroys microorganisms on inanimate objects, not living tissue.
Disinfection	A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.
Germicide	An agent that destroys microorganisms. Can be used on living tissue and inanimate objects.
High-level disinfection	A process that eliminates all pathogenic microorganisms on devices with the exception of small numbers of bacterial spores. Typically abbreviated as “HLD".
High-level disinfectant	Traditionally defined as complete elimination of all microorganisms except for small numbers of bacterial spores. Typically abbreviated as “HLD".
Manufacturer's instructions for use (IFU)	Written recommendations and/or guidelines provided by the manufacturer of a device that provides instructions for operation and safe and effective reprocessing.
Medical device	Instrument, apparatus, material, or other article intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment, or alleviation of disease, injury, anatomical modification, etc.
Minimum Effective Concentration (MEC)	The minimum concentration of HLD chemical required for effective high-level disinfection.
Procedure	A document or set of activities that describes tasks HCP must perform to achieve requirements set forth in a policy or desired outcomes.
Semi-critical device	Per Spaulding classification scheme, devices that contact mucous membranes or nonintact skin.
Sterile	The complete absence of all forms of microbial life.
Sterilization	The complete elimination of all forms of microbial life.

B. Spaulding Classification Scheme

The Spaulding classification scheme is a rational approach to disinfection and sterilization of reusable patient

care equipment and/or devices. Based on the degree of risk of infection involved in the use of items, the scheme divides reusable patient care items into three distinct categories: 1) critical; 2) semi-critical; 3) non-critical. Critical items require sterilization; semi-critical items require at least high-level disinfection unless sterilization is feasible and in alignment with the item's manufacturer's IFUs; non-critical items require low level disinfection as instructed by the item's manufacturer's IFUs.

In conjunction with manufacturer's IFUs, refer to the Spaulding classification scheme to determine the level of reprocessing required. Please contact Infection Prevention for questions related to the Spaulding scheme and/or IFUs.

Critical Items: require sterilization	Enter/contact normally sterile tissue or the vascular system. Examples include but not limited to surgical instruments, certain catheters, implants, laparoscopes, arthroscopes.
Semi-critical Items: require at least high-level disinfection	Contact intact mucous membranes or non-intact skin. Examples include but not limited to some endoscopes, endocavitary probes, diaphragm fitting rings, laryngeal blades.
Non-critical Items: require low-level disinfection	Contact intact skin but not mucous membranes. Examples include but not limited to bed pans, blood pressure cuffs, and stethoscopes.

C. Departmental Responsibilities

1. Reprocessing Department Directors, Managers, and/or Designees
    a. Shall compile a list of all healthcare personnel (HCP) that perform instrument reprocessing and keep the list updated.
    b. Shall compliant a list of all instruments/devices that are reprocessed in their units/clinics and keep that list updated.
    c. Shall ensure that reprocessing activities, including cleaning, decontamination, inspection and HLD are performed by competent, qualified personnel.
    d. Shall be able to readily access manufacturer's instructions for use (IFUs) and/or user's manuals for devices, equipment, and supplies.
    e. Shall oversee compliance with policy, procedure, and IFUs related to cleaning, decontamination, inspections, HLD and documentation activities.
    f. Shall ensure that all reprocessing equipment receives routine care, cleaning, and quality assurance testing in accordance with manufacturer's IFU.
    g. Shall ensure that education, training, and competency verification is provided to personnel upon hire and at least every 365 days. Competencies may require more frequent documentation than yearly, such as when new endoscopic models, new processing equipment or products (e.g., new high-level disinfectants) are introduced. For additional details see "HLD Competency and Training" section below.
    h. Shall ensure that breaches in reprocessing activities are reported via a SAFE report, to Infection Prevention and other appropriate leadership and investigated.
    i. Shall ensure reprocessing departments are clean and accommodate reprocessing activities in accordance with the Occupational Safety and Health Administration (OSHA).

j. Shall ensure reprocessing department procedures are reviewed on a regular basis and as needed. Collaborate with appropriate stakeholders, including Infection Prevention, prior to implementing new or revised procedures.

k. Trial and/or purchase of reusable items or equipment used for HLD are done in collaboration with Infection Prevention.

l. Documentation records (paper logs, electronic logs, etc.) are retained for 5 years.

2. Environmental Services Department

   a. Cleaning and disinfection of reprocessing environment is performed daily with an EPA-registered disinfectant cleaning solutions.

   b. Decontamination areas are cleaned and disinfected each shift.

3. Infection Prevention Department

   a. Investigates reports of inadequate HLD and addresses findings with appropriate stakeholders promptly.

   b. Provides consultation to clinical units and reprocessing departments with decisions regarding cleaning, decontamination, HLD, documentation, and relevant tracking of reusable semi-critical items.

   c. Conducts routine rounds using a designated HLD survey tool to evaluate reprocessing environments and activities. Reports findings to appropriate leadership and collaboratively addresses areas of concern to ensure safe and effective reprocessing principles.

D. HLD Chemicals

1. Only HLD chemicals that have been approved by the Infection Prevention department may be used. Please refer to the Infection Prevention policy: Endoscope for additional details. The current approved HLD chemicals:

   a. Cidex® glutaraldehyde

   b. Cidex® ortho-phthalaldehyde (OPA)

   c. Revital-Ox Resert®

   d. Rapicide PA® for selected automated endoscope reprocessors (AERs) only

   e. Rapicide® glutaraldehyde for selected AERs only

   f. TD-5 for the TD 100® AER

   g. Cidex OPA-C for Evotech AER

E. HLD Competency and Training

1. All health care personnel (HCP) who perform HLD activities are required to attend the initial in-person HLD workshop as soon as possible after assignment of HLD responsibilities to the HCP. Thereafter and at least every 365 days, HCP is required to attend the HLD refresher class (in-person and WebEx options). Registration for the workshop and the refresher is via LMS. Contact Infection Prevention or LMS for workshop and class.

2. Please see the Infection Prevention's Instrument Reprocessing website for the most current competency form for the HLD processes performed at your specific area and specific devices.

3. Initially, there are four elements that must be completed in order to meet UNCH's requirements for HLD competency:
    a. Training
        i. HLD Workshop and on-the-job practice with a competent person
    b. Demonstration
        i. Able to perform HLD with no assistance
    c. Observation
        i. Competent person observes your entire process
    d. Documentation
        i. Competent person completes your competency form
4. Yearly (at least every 365 days), three elements must be completed:
    a. Demonstration
    b. Observation
    c. Documentation
5. All HLD HCP must take the LMS module "Color Blindness for High-level Disinfection Staff."

IV. Procedure

Reusable semi-critical items that cannot be sterilized (per manufacturer's IFUs) must be high-level disinfected between each use in order to render them safe.

A. Basic Steps of HLD Instrument Reprocessing

1. Transport, decontamination and personal protective equipment (PPE)
    a. Transport of used, contaminated patient care instruments:
        i. At point of use, instruments should be wiped to remove gross soil and/or blood. Gauze moistened with water or an approved disinfectant wipe may be used. Manufacturer's IFUs for precleaning/pretreating must be incorporated into the point of use cleaning.
        ii. Lumens should be flushed/suctioned according to manufacturer's IFUs.
        iii. Transport used instruments in a leak-resistant container marked "biohazard".
        iv. Type of transport container depends upon the type of instrument transported:
            - Bins should have lids.
            - Carts should be enclosed or covered.
            - Impermeable bags marked "biohazard". A specimen bag marked biohazard or plastic bag with a biohazard label is appropriate if no sharps are present.
        v. Used instruments must be kept moist until they are transported to the appropriate decontamination area (i.e., central processing department, clinic instrument reprocessing room). Moisture may be maintained by applying an approved moistening product or placing a water-moistened towel or gauze over the instrument(s). Do not use saline for this purpose.

b. Decontamination and PPE

i. Wear appropriate PPE in the decontamination area. Remove PPE and perform hand hygiene before leaving the decontamination area.

ii. Required PPE includes:

- Fluid-resistant gown tied in the back
- 12" (or longer) extended cuff nitrile gloves
- UNCMC Environmental Health and Safety (EHS) department approved face shield
- EHS approved safety glasses or goggles (ANSI-approved)
- For Trophon reprocessing activities gloves alone are required.

iii. Manufacturer's IFUs for decontamination must be followed for all instruments reprocessed.

iv. Visually inspect all parts of all instruments for damage prior to decontamination.

- Remove damaged instruments from service, tag "damaged, do not use", and place in a container marked biohazard.
- Notify appropriate leadership of damage and removal from service.

v. Measure, mix, label, dispense, and discard detergent solutions appropriately and according to manufacturer's IFUs.

vi. Do not reuse detergents.

vii. Single use brushes are preferred and must be discarded after one use.

viii. Reusable brushes must be reprocessed after each use. Discard when worn.

ix. All brushing is performed under water to decrease the risk of exposure to HCP.

x. Dissemble all instruments that lend themselves to disassembly before cleaning.

xi. Observe soak times as prescribed by detergent labels.

xii. Rinse decontaminated instruments thoroughly to remove organic material, paying special attention to lumens and/or hard-to-reach areas.

xiii. Dry thoroughly to avoid dilution of HLD chemicals.

xiv. When appropriate, use a lighted magnifying glass to inspect instruments after decontamination to ensure that all organic soil and/or material has been removed. Repeat the decontamination process if any organic soil remains.

xv. Clean and disinfect work stations and cleaning equipment daily and as needed with an EPA-registered disinfectant following disinfectant manufacturer's IFUs.

2. HLD Quality Control and Minimum Effective Concentration (MEC)

a. Perform quality control checks using test strips and/or other manufacturer's testing materials according to manufacturer's IFUs.

b. Use techniques, including test strip management practices, timing, and frequency, strictly according to manufacturer's IFUs for the product(s) in use.

c. Keep test strip containers completely closed at all times. Exposure to air can cause MEC test strip failures.

d. Test strip bottles/vials must have opened and expiration dates clearly marked with an indelible felt-tipped pen. A written expiration date cannot exceed a manufacturer's stamped expiration date.

3. High-level Disinfect
    a. Measure, mix, and use HLD chemicals according to manufacturer's IFUs.
        i. Soak times are according to manufacturer's IFUs with the exception of Cidex® Activated Dialdehyde solution (glutaraldehyde).
            - Cidex® Activated Diadehyde (glutaraldehyde) solution is approved by UNCMC Infection Prevention for a 20 minute soak time at 20°C in accordance with major instrument reprocessing standards (CDC, 2008; add AAMI).
        ii. Reusable HLD chemicals are used for the length of days allowed per manufacturer's IFUs.
    b. Contain solutions in an appropriate and compatible container and keep covered at all times.
    c. Secondary containers must be labeled:
        a. Product name
        b. Hazard information (can be from the SDS)
        c. Open and expiration dates of chemicals
    d. Use automated reprocessing equipment (automated endoscope reprocessors [AERs], Trophons) whenever possible.
    e. Items that are not validated for reprocessing in an AER are reprocessed in manual soak stations. Please contact Infection Prevention for additional validation information and details.
4. Final Rinses and Drying
    a. After appropriate soak time in a manual soak station, thorough and complete rinsing with tap water according to HLD chemical manufacturer IFUs.
        i. Do not reuse rinse water.
        ii. Ensure that channels and/or lumens are adequately flushed with clean water.
    b. Ensure channels and/or lumens are flushed with 70% ethyl or isopropyl alcohol.
        i. Follow alcohol flush with medical-grade forced air (instrument air) until completely dry.
5. Documentation
    a. The HLD documentation log used by a particular area is dependent upon which chemical, test strip, and process is used. Please consult with Infection Prevention to determine which log is required for your area.
        i. Keep the most current logs, i.e., current month, within the reprocessing area. Keep all logs for 5 years.
        ii. Documentation, i.e., logs, must include the following elements:
            - Test/reprocessing date
            - HLD chemical temperature
            - Test strip lot number

- Date test strips expire
- Test strip quality control pass or fail if required by manufacturer's IFUs
- Date HLD chemical expires
- MEC pass or fail for every reprocessing occurrence

6. Storage
    a. High-level disinfected items shall be stored in a manner that prevents recontamination, e.g., in a clean drawer, covered with a clean probe cover, etc. Consult with Infection Prevention for appropriate methods. Ideally, high-level disinfected items should not be stored in the instrument reprocessing room.
    b. Ideally, high-level disinfected items should not be stored in the instrument reprocessing room.

B. Trophons

1. Trophon technology consists of stand-alone device that high-level disinfects selected vaginal and rectal endocavitary probes. Note that only Trophon2 is validated to HLD rectal endocavitary probes.
    a. Please see the Infection Prevention's Instrument Reprocessing website for the most current Trophon log and competency form.
    b. The Trophon shall be operated in accordance with the manufacturer's IFUs and user's manual to include proper dating of cartridges and chemical indicators, correct storage of these items, and prescribed periodic maintenance.

C. Ultrasound Endocavitary Probes

1. When used on intact skin (e.g., central line puncture site, needle biopsy) and therefore a noncritical device, low-level disinfection with an EPA-registered disinfectant is adequate. Refer to the product manufacturer for the recommended cleaning product.
2. When used on non-intact skin or mucous membranes and therefore a semi-critical device, the Infection Prevention policy: High-Level Disinfection - Manual Reprocessing of Reusable Semi-Critical Devices shall be followed. The use of an US probe cover or sheath does not preclude HLD.

V. References

Flexible and semi-rigid endoscope processing in health care facilities; Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST91: 2015.

CDC guideline for disinfection and sterilization in health-care facilities; Rutala WA, Weber DJ, and Healthcare Infection Control Advisory Committee (HICPAC). 2008.

Multi-society guideline on reprocessing flexible GI endoscopes: 2016 update

High-level Disinfection and Sterilization BoosterPak, 2017, The Joint Commission.

Ambulatory Surgical Center Infection Control Survey Worksheet, Center for Medicare and Medicaid Services, 2015.

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes, 2016.

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes, 2016.

VI. Related Policies

Infection Prevention Policy: Endoscope

Infection Prevention Policy: Environmental Services

Infection Prevention Policy: Sterilization of Reusable Patient Care Items

VII. Responsible for Content

Infection Prevention Department

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Patricia Ness: Clin Nurse Education Spec	04/2020
	Thomas Ivester: CMO/VP Medical Affairs	04/2020
	Emily Vavalle: Director, Epidemiology	04/2020
	Sherie Goldbach: Project Coordinator	04/2020

Applicability

UNC Medical Center