Georgia Regents Medical Center
Policy Library

High Level Disinfection

Policy Owner: Epidemiology

POLICY STATEMENT
All areas within Georgia Regents Medical Center (GRMC) reprocessing semi-critical devices and equipment will use high level disinfection methods according to the latest industry standards and manufacturer’s instructions for use (IFUs).

The following provisions will be used at a minimum, but each individualized area may have more specific procedures as deemed appropriate. Certain semi-critical devices are approved for intermediate level disinfection and thereby excluded from this policy as they are addressed in the policy on low level disinfection.

AFFECTED STAKEHOLDERS
Indicate all entities and persons within the Enterprise that are affected by this policy:

☐ Administrative Services
☒ Hired Staff
☒ Housestaff/Residents & Clinical Fellows
☒ Leased staff
☒ Medical Staff (includes Physicians, PAs, APNs)
☒ Patient Care Services (Nursing, PCT’s, Unit Clerks)
☒ Professional Services (Laboratory, Radiology, Respiratory, Pharmacy; etc.)
☒ Vendors/Contractors
☐ Other: Include any other stakeholders not listed above.

DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Bioburden</td>
<td>Degree of microbial contamination or microbial load; the number of microorganisms contaminating an object.</td>
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<tr>
<td>High Level Disinfection</td>
<td>A process which destroys all microorganisms, with the exception of high numbers of bacterial spores. This process may use chemicals or high heat temperatures to achieve appropriate disinfection.</td>
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<td>Proteolytic Enzymatic Cleaner</td>
<td>A detergent that contains protease enzymes which breakdown proteins found in blood, mucous and other organic matter.</td>
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<tr>
<td>Semi-critical Devices</td>
<td>Devices that touch mucous membranes and/or non-intact skin, but do not enter sterile tissues or the vascular system.</td>
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Sterilization | The complete elimination of all forms of microbial life including spores.

PROCESS & PROCEDURES

General Provisions for All HLD

1. Any instrumentation which comes into contact with mucous membranes and/or non-intact skin will be reprocessed using high level disinfection; and when directed by the manufacturers’ instructions for use.

2. If an item or equipment is brought in from another department and appropriate processing in the previous department cannot be verified, the item is to be reprocessed according to manufacturers’ instructions prior to use.

3. Items such as endoscopes, laparoscopes, and arthroscopes which enter sterile tissue and body cavities should be sterilized rather than high level disinfected; see the Sterilization Policy for these devices.

4. All manufacturers’ instructions for use for both mechanical and chemical methods of high level disinfection will be followed whenever possible. Ensure material compatibility with the disinfectant prior to high level disinfection.

5. A log book will be maintained at the point of reprocessing so that items can be traced back to the point of use if necessary. The log book will contain the patient’s name, medical record number, date of service, instrument used with serial number or other identifier if known, procedurist, and procedure location.

6. All items undergoing high level disinfection will be first decontaminated according to manufacturers’ instructions for use using an approved proteolytic detergent to render the item free of all visible organic matter and bioburden.
   a. Pre-cleaning of the device at the point of use is performed using an approved, ready-to-use proteolytic cleaner. The device is then moistened...
with the ready-to-use proteolytic cleaner and transported to an approved
decontamination area for further cleaning. Transport is done in a manner
to denote that the device has been used and to prevent occupational
exposure. A case cart or cleanable, rigid container is preferred when
possible. The same container may be used to transport used and
reprocessed items provided that the used items are within a biohazardous
bag within the container during transport and that the container is
disinfect ed with the hospital approved disinfectant wipe prior to being
used for transport of reprocessed items.

b. Donning appropriate PPE, mix the disinfectant according to
manufacturer’s instructions, and disassemble all removable parts to
prepare them for cleaning.

c. Using standard precautions, all surfaces of the instrument (internal and
external) are to be thoroughly cleaned using appropriately sized brushes.
Brushes used during the cleaning process are single use only and
discarded after each use. Brushes provided by the manufacturer for loaner
instrumentation and equipment must be new and single use only; if not,
GRMC provided brushes will be used.

d. For flexible endoscopes and other lumened items, a strip test will be
performed to check for cleaning efficacy.

e. Following each cleaning process, contaminated detergent should be
discarded in a drain connected to the municipal sewer system.

7. Once cleaning is complete, all instrument surfaces and lumens will be rinsed with
large amounts of tap water and dried, purging water from all channels and
lumens to avoid the potential mixing of incompatible chemicals or dilution of
disinfectant from the presence of excess tap water.
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8. Any items which have been high level disinfected are stored in a manner to prevent contamination.
   
   a. Storage of devices in original cases padded with foam is not acceptable for storage between patient uses as the foam is not cleanable and thereby re-contaminates the device. These cases should only be utilized for transport of the device back to the manufacturer only when servicing is scheduled or required. When sending out for servicing, the device must be decontaminated at a minimum before sending to the manufacturer ensuring that it is safe for handling.
   
   b. Immediately following drying, scopes are covered with a clean, open-ended sheath and labeled with the reprocessing date. All endoscopes are stored hanging in a vertical position or per manufacturer’s instructions for use to minimize the potential for the accumulation of residual moisture. Storage cabinets are to be vented, closable, and made of material to withstand low level disinfection and prohibit microbial growth from any residual moisture draining from hanging scopes.

9. Coiling of flexible endoscopes is avoided during all stages of handling to prevent damage to the fiberoptics.

Gluteraldehyde Use for HLD

1. The use of gluteraldehydes for high level disinfection will be avoided when other manufacturer approved disinfectants are available. Non-gluteraldehyde based disinfectants which have been approved by both the equipment manufacturer and the Infections Committee will be used instead to minimize patient and occupational exposure to known carcinogens.

2. Decontamination rooms where gluteraldehydes are used are required to maintain a negative pressure relative to surrounding areas, and must have a minimum of
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ten air exchanges per hour. A gluteraldehyde vapor control system may be used in certain settings upon approval by Hospital Epidemiology and only if the user department/area can demonstrate competency.

3. When using a gluteraldehyde for high level disinfection, record the date of activation and date of expiration per the manufacturer in a log book, and place a label on the storage container for the activated gluteraldehyde. A quality monitoring log book is maintained with the aforementioned information along with a list of instruments processed in the user departments for monitoring and tracking purposes.

4. The solution is checked with the appropriate solution test strip daily when in use and prior to each use to ensure solution efficacy. (If dilution is suspected, additional testing is done.) This information is also recorded in the log book.

5. Other information as listed under general provisions will also be logged so that items reprocessed can be traced back to the point of use if necessary.

6. If the test strip fails, or the solution has reached its expiration date the solution will be discarded and a new batch of solution will be prepared and logged accordingly. Gluteraldehydes are disposed of by pouring these chemicals down a drain connected to the municipal sewer system with the water running. Personal protective equipment (i.e. gluteraldehyde resistant gown, nitrile or butyl gloves with extended cuffs, masks and goggles) is used when disposing of gluteraldehydes.

6. After solution efficacy is verified, using appropriate personal protective equipment (i.e. nitrile or butyl rubber gloves with extended cuffs, gluteraldehyde resistant gown, goggles), completely immerse the instruments and any removable parts in the gluteraldehyde. Ensure that the lumens of hollow instruments are filled with solution by injecting gluteraldehyde into them under the surface to
prevent splashes and force out any trapped air bubbles so the gluteraldehyde comes in contact with all instrument surfaces.

7. Once soaking has begun, no additional items can be added. Cover the container and allow the instruments to soak for the established time per the gluteraldehyde manufacturers’ instructions (i.e. a soak time of 45 minutes for Cidex and 12 minutes for Cidex OPA). Secure fitting lids are used for the storage of gluteraldehydes and the lids will be kept on the containers as much as possible to minimize vapor release.

8. After disinfection is completed, copious amounts of sterile water (for bronchoscopes and endoscopes that pass through sterile tissue) or tap water are used to remove the gluteraldehyde solution from both the internal and external surfaces of the instruments. Follow with a 70% alcohol rinse, suctioning/irrigating through all channels to facilitate drying and prevent microbial growth.

9. Direct compressed air through the channels when possible to maximize drying of the lumens and store as above.

10. Safety data sheets specific to the gluteraldehyde manufacturer must be maintained in the department at the point of use. Personnel handling gluteraldehydes should be familiar with the location of the safety data sheets in the event of occupational exposure for immediate first aid. Occupational exposures to gluteraldehyde should be reported to Employee Health and Wellness as any other first report of injury. After immediate response, the department manager should also report the exposure to Hospital Epidemiology who will assist Employee Health and Wellness in the exposure investigation if necessary.
Automated Reprocessor Use for HLD (Peracetic Acid)

1. When manufacturer instructions for use allow, items requiring high level disinfection will be disinfected via an automated reprocessor (Steris System 1E and Medivator DSD Edge) which employs the use of peracetic acid as a disinfectant.

2. Diagnostic testing will be performed daily to ensure the automated reprocessor is functioning properly. With each load, appropriate chemical test strips will be used to ensure the disinfecting efficacy of each cycle.

3. A log book will be maintained for automated units to document items disinfected, cycle parameters, test strip results, and other information as listed under general provisions so that items reprocessed in automated units can be traced back to the point of use if necessary.

4. Cycle parameters established by the manufacturer such as time, temperature, and concentration, must be verified upon completion of the cycle, and if these parameters are found to be outside of the acceptable range, the item cannot be used and must be reprocessed.

5. If a mechanical failure is encountered or the automated unit is operating outside of normal parameters, Biomedical Engineering will be contacted and the unit will be removed from service until it can be repaired and functionality is restored. The department must monitor and report both mechanical and chemical failures monthly to Hospital Epidemiology for tracking and trending.

6. Items will be cleaned following the aforementioned process and all removable parts disassembled prior to being placed into the automated units for high level disinfection. For endoscopes, and other lumened items, appropriate quick connectors, trays, hoses, and adaptors will be used to ensure the automated units can pump disinfectant throughout lumened chambers.
7. Near the end of the cycle, automated units will complete a rinse phase removing all disinfectant from the instruments’ surface and purging all residual disinfectant from any channels or lumens.

8. Instruments processed in the Steris System 1E for non-immediate use are considered high level disinfected and will be immediately removed from the reprocessing tray, dried and stored as above and according to manufacturer’s instructions.

9. Instruments processed in the Steris System 1E for immediate use (chemical sterilization) will remain in their reprocessing tray until they reach the point of use and personnel remove them from the tray to the sterile field using sterile gloves and towels to maintain sterility.

HLD Competency:

Standardized competencies will be developed and utilized for personnel performing HLD. Competency documentation will be maintained as per GRMC policy.

Individual managers overseeing areas reprocessing multiple semi-critical devices and equipment or utilizing multiple mechanisms of reprocessing who are not certified or credentialed in HLD are required to demonstrate competencies required of the positions they oversee.

REFERENCES, SUPPORTING DOCUMENTS, AND TOOLS
Association for the Advancement of Medical Instrumentation (AAMI) standards

RELATED POLICIES
Disinfection Level Determination
Laryngoscope Reprocessing Policy
Sterilization Policy
High Level Disinfection

Policy Owner: Epidemiology

APPROVED BY
Chief Executive Officer, Georgia Regents Medical Center  Date: 03/18/2016