High-Level Disinfection (HLD)/Sterilization Survey Checklist with Answers		Met	Not Met	Not Applicable
Survey Date:	**Surveyor:**			
Area:				
Area Manager:				
Person Performing Assessment:				
1. Training-Infection Control Policies and Procedures				
a. Staff has access to Infection Control policies.	Staff can demonstrate how to access Infection Control policies.			
b. Staff can articulate the procedure for reprocessing semicritical/critical medical and surgical devices.	Appropriate staff are well informed and can articulate the reprocessing steps.			
c. Personnel assigned to reprocess semicritical/critical devices receive device-specific reprocessing instructions to perform proper cleaning and high-level disinfection or sterilization.	All staff performing HLD or sterilization must be properly trained and their performance subject to periodic review and continuing education.			
d. Competency testing should be done on a regular basis (beginning of employment, annually) of all personnel who reprocess semicritical/critical devices or instruments.				
e. Other components of an education program include: PPE; OSHA bloodborne pathogen training; reprocessing procedures; mechanisms of disease transmission; maintenance of a safe work environment; safe handling of HLD/sterilant; waste management.				
f. For Central Processing (CP), are staff certified?				
g. Are staff trained on all new instrumentation, devices and equipment?				
h. Policy and procedure for loaners?	Loaners should be in CP 24-48 hours before use to ensure decontamination and sterilization.			

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2. Instrument Decontamination/Pre-Cleaning				
a. Items are thoroughly pre-cleaned and decontaminated with detergent according to manufacturer instructions and/or evidence-based guidelines prior to high-level disinfection or sterilization. Precleaning (where appropriate such as GI, Bronchoscopy) should be performed at the point-of-use (e.g., OR, GI procedure room) before bioburden has an opportunity to dry. For example, immediately after removing the scope from the patient, wipe the insertion tube with a wet cloth or sponge in the freshly prepared detergent solution. Then place the distal end of a scope into the detergent solution and suction a large volume until clear.	Staff can demonstrate understanding of the cleaning steps and the rationale for meticulous cleaning.			
b. Items are disassembled (e.g., suction valves, air water valves) and thoroughly cleaned (e.g., lumens are brushed under water with a detergent solution). Use cleaning brushes appropriate for the size of the channel or port (bristles should contact surfaces). Cleaning (flush/brush) should ideally occur within one hour of use. Clean the external surfaces and accessories of the device by using a soft cloth, sponge or brush. Transport the soiled item to the reprocessing area in a closed container that prevents exposure.	Must remove all organic and inorganic residue as these materials could interfere with the effectiveness of the HLD or sterilization procedure. All items for sterilizaton/HLD must be actively cleaned with brushes, sponges or clothes and detergent solution. Wiping with a germicidal wipe is acceptable for only a vaginal probe.			
c. Discard detergent or enzymatic cleaner after each use.	Detergents are not microbicidal and will not retard microbial growth.			
d. Leak test is done before immersion of flexible endoscope in the reprocessing solution to minimize damage to parts of the scope not designed for fluid exposure.	Leak test detects damage to the interior/exterior of the endoscope			
e. Items are managed consistent with OSHA regulations, manufacturer's written instructions for use, and hospital policy.	Example: dirty instruments must be transported from point-of-use to instrument processing area in a leak-proof container marked "biohazard."			
3. High-Level Disinfection				

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a. Medical instrument and devices are visually inspected for residual soil and recleaned as needed before high-level disinfection.	Soil/organic material influences the effectiveness of HLD/sterilization process.			
b. HLD equipment (e.g., AER) is maintained according to manufacturers' instructions and/or evidence-based guidelines.	AERs are maintained and logs kept of maintenance.			
c. Chemicals used for HLD are prepared according to manufacturers' instructions, infection control policy, and evidence-based guidelines. The correct temperature and time are used.	Only FDA-cleared HLDs are used.			
d. Chemicals used for HLD are tested for the minimum effective concentration (MEC) according to manufacturers' instructions and/or evidence-based guidelines and are replaced before they expire. Use only FDA-cleared HLDs. Check the solution at least daily and discard if the concentration is less than the MEC.	Logs are kept for all HLD processes, including test strip results. Containers must be covered and labeled with chemical name, hazard information and expiration date.			
e. Chemicals used for HLD are documented to have been prepared and replaced according to manufacturers' instructions and/or evidence-based guidelines.				
f. Semicritical equipment is high-level disinfected according to manufacturer's instructions and/or evidence-based guidelines and according to the hospital's Cleaning, Disinfection, and Sterilization of Patient-Care Items policy.				
g. Items that undergo HLD are dried before re-use.				
h. HLD logs are properly maintained (e.g., date, MEC result).	Logs must be kept on all HLD processes.			
i. The test strip bottle is dated and not used beyond the use-life.				

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j. Individuals with HLD responsibilities have attended a class or training session.	Class or training sessions are offered regularly by the Infection Preventionists or area supervisor. Individuals must demonstrate knowledge and competence in instrument reprocessing to include disassembly, cleaning, monitoring and documentation.			
k. Individuals with HLD responsibilities should have the ability to interpret color differences as test strips for MEC change color. In order to meet the Human Resources standards that an employee fulfills the expectations of their job description, we ask that everyone who performs HLD place an attestation of whether or not they are color blind in their personnel file. If color-blind they should be assess by OHS.	Individuals performing HLD have attestation whether or not they are color blind on file at the clinic. Clinics are responsible for keeping this protected health information in a HIPAA-compliant manner.			
l. Flexible endoscopes should be leak tested before every high-level disinfection.	Detects a damaged endoscope.			
m. The HLD is actively perfused into the channel with a syringe to ensure exposure of the contaminating microorganisms to the HLD.	No HLD will perfuse into the channel unless forced by a syringe/mechanically because the air pressure in the channel is stronger that the fluid pressure at the fluid-air interface.			
n. After HLD, rinse endoscopes and flush channels with sterile water, filtered water or tapwater followed by a rinse with 70-90% alcohol.	Prevents adverse effects on patients associated with the HLD retained in the endoscope (e.g., disinfectant induced colitis).			
o. Hang or store endoscope or other semicritical item in a manner that presents recontamination (cabinet, hook on wall in clean holding area) or damage (not carry case).				
p. As applicable, sterilize or HLD both the water bottle used to provide intraprocedural flush solution and its connecting tube at least once daily. After sterilizing or HLD the water bottle, fill with sterile water. Alternatively, use sterile disposable bottles.				
q. HLD should be done in an area that provides a safe environment for HCP.	Use air-exchange equipment (e.g., ventilation system, outexhaust ducts) to minimize exposure of all persons to potentially toxic vapors (e.g., glutaraldehyde). Do not exceed the allowable limits of the vapor concentration of the HLD (e.g., OSHA).			

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r. Is an automated system used to reprocess the semicritical item such as an automated endoscope reprocessor (AER)? If an AER is used, have the HCP been trained on how to attach all channel connectors according to the manufacturer's instructions?	AERs standardize and automate the reprocessing steps. The endoscope must be properly attached to the AER to ensure exposure to all internal surfaces to the HLD.			
s. Is PPE (gloves, gown, eyewear, faceshield, etc) made available and used appropriately to protect workers from exposure to chemicals?				
t. If ERCP procedures are done, will enhanced reprocessing of the duodenoscope be implemented.	Enhanced reprocessing minimizes risk of infection (e.g., ETO, double HLD, etc).			
u. If probe cover is used (vaginal probe, rectal probe), the use does not reduce the level of microbial contamination. Use a high-level disinfectant at the FDA-cleared exposure time (or exposure time recommended by professional organization guidelines).	Probe covers (e.g., condoms, sheaths) fail at a rate of 2-81% and become contaminated with the microbial flora at the site.			
v. The HLD is actively perfused into the channel with a syringe to ensure exposure of the contaminating microorganisms to the HLD.				
w. Hospitals should have a strategy (e.g., tagging, storage covers for patient-ready devices) that prevents patient exposures to contaminated devices.	The use of a tagging system separates processed from non-processed items and minimizes the use of a semicritical item that has not been reprocessed and prevents patient exposures to a non-reprocessed semicritical item.			
4. Sterilization				
a. Sterilizers-chemical and biological indicators (BI) are used appropriately. Steam is the preferred method for sterilizing critical devices. Do you follow the sterilization times, temperatures and other operating parameters (e.g., gas concentration, humidity) recommended by the manufacturer of the instruments, the sterilizer, and the container or wrap used? Use low-temperature sterilization technologies for equipment that is heat or moisture sensitive.	Internal chemical indicators (CI) must be used in each package to be sterilized; the chemical indicator must be examined before the contents are used. CI are heat or temperature sensitive inks that change color when a germicidal-related parameter (such as temperature) has been achieved.			

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b. Biological indicators run at least weekly. Do not use processed items if the physical or chemical indicators suggest inadequate processing.	Biological indicators are to be run at least weekly (in CP should be run at least daily) and must be used with each load containing implantable devices.			
c. Sterilization logs are accurate and up-to-date.	Written records of each load should be kept.			
d. Sterile packages are inspected for integrity and compromised packages are reprocessed.	Instruments in torn, wet, or damaged sterilization pouches must be re-sterilized.			
e. Physical monitor printout is checked and signed/initialed by operator.	Ensure time/temperature is correct (e.g., 132^{o}C for 4 minutes).			
f. Immediate use steam sterilization is used infrequently (e.g., <5% of steam sterilization cycles) and not used for implants except in cases of emergency when no other option is available.				
g. Chemical indicators are checked prior to use.	Ensure indicators have changed color, which indicates processing has occurred.			
h. Instrument tracking system available where applicable.				
i. Load the sterilizer properly…peel packs and lighter items on top shelf; peel packs and linen packs on edge (not horizontal); no stacking of pans.				
j. Are manufacturers' written instructions for use (IFUs) available and followed (e.g., extended sterilization times).				
k. Individuals with HLD responsibilities have the ability to interpret color differences.				
l. Water quality meets manufacturers requirements.				
m. Implants are monitored with a BI and a Class 5 CI; ideally, not released until results of BI available; traceable to the patient.				
n. IUSS practices-items are appropriately cleaned; use of closed validated flash containers; all parameters documented and traceable to the patient; aseptic transportation to point-of-use; implants only in emergency situation; IUSS not used as a substitute for sufficient instrument inventory.				

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o. Storage conditions-cleanable surfaces; bottom shelves are solid and 8-10" above the floor; heavy wrapped items are not stacked; shelf-life is event related; controlled area (appropriately attired persons only) signs posted; 18" below the ceiling; 2" from outside walls. Ensure the storage area is well-ventilated and it provides protection against dust, moisture, insects and temperature and humidity extremes.				
p. Instrument set weighs not over 25 pounds, scale available.				
q. Packaging-ensure that the packaging material are compatible with the sterilization process. Ensure that packaging is sufficiently strong to resist punctures and tears to provide a barrier to microorganisms and moisture.				
5. General Decontamination/HLD/Sterilization				
a. Proper PPE is worn when processing dirty equipment.	Water-proof or water-resistant gown, disposable gloves (nitrile if performing HLD activities), and full-face protection must be worn when processing dirty instruments.			
b. Competencies are maintained for cleaning, disinfection and sterilization processes.	Records of staff training must be documented. HLD competency is evaluated at commencement of employment and at least yearly thereafter.			
c. HLD, decontamination, and/or sterilization is performed in appropriate environment.	HLD, decontamination and/or sterilization may not be performed in a patient care area. If using glutaraldehyde proper ventilation should ensure the PEL is not exceeded.			
d. Areas used for cleaning or disinfection flow from dirty to clean.	The area must have a definite work flow from dirty to clean to prevent contamination of equipment.			
e. There is a procedure in place for identification and recall of inadequately sterilized or high-level disinfected instruments.	Infection Prevention department must be notified immediately about instrument recall.			
f. After sterilization or high-level disinfection, devices and instruments are stored in a designated clean area so sterility/cleanliness is not compromised.	Sterilized and high-level disinfected items should not be stored in instrument processing areas whenever possible.			

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g. The ventilation is consistent with guidelines (soiled-negative, 10AC/hr; clean/sterile area-positive, 10AC/hr). Hand hygiene facilities are conveniently located in clean and decontamination areas.	Ideally, the ventilation standard would be met in areas where semiciritcal/critical instruments are reprocessed. However, only CP and GI or new/renovated facilities may meet these criteria.			
h. Areas that use HLD should have a spill containment plan for the chemicals in the area. The plan should include information from the Safety Data Sheet. The plan should also include written procedures for actions to contain the spill and deactivate the chemical, a communication and evacuation plan.				
6. Quality Assurance				
a. A preventive maintenance should be in place for automated equipment such as AERs.				
b. An individual in the area should be designated and assigned to monitor compliance with the reprocessing protocol.				
c. Monitor mechanical cleaning equipment (e.g., washer disinfector) at least weekly, as applicable; each sterile product labeled with a lot control identifier (may only be applicable in CP); sterilization records for each cycle are complete.				
d. Sterilizer process monitoring-routine monitoring of sterilizer efficacy; correct Process Challenge Device (PCD) used for each cycle; Bowie Dick test daily. What action taken when physical indicator (PI), CI or BI indicates failure? Recall process in place and reported to Infection Control? Vacuum sterilizers will likely not be available in ambulatory facilities, thus, Bowie-Dick will not be used.				
e. Conduct infection control rounds periodically in high-risk reprocessing areas (e.g., GI, CP, Urology). Document all deviations from policy and request deficiencies corrected with 30 days (and immediately if a patient safety issue).				

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f. For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature-requires a integral printer); the operator's name or initials; and the results of the physical, chemical and biological indicator.				
g. Retain sterilization records (PI, CI, BI) for a time period that complies with standards (e.g., 3 years), statues of limitations, and state and federal regulations.				
7. General Issues				
a. Areas free of dust, dirt, soil, trash, odors, clutter and hazards (fixtures, walls, ceilings, floors).	Ceiling tiles all intact, clean, dry and no stains.			
b. Areas and furnishings are in good repair.	Paint intact, cabinet doors functioning properly, no rips, holes, or cracks in vinyl upholstery.			
c. Staff food and drinks are placed in appropriate areas.	Stored away from patient care areas and in compliance with NC OSHA blood borne pathogen regulations.			
8. Safety				
j. Safety Data Sheets (SDSs) (formerly "MSDSs")	Staff should know how to access SDSs.			
k. Eyewashes	Checked per policy (monthly, quarterly) and documented.			
l. Medical equipment	Medical equipment is appropriately tagged and tags are not expired.			
9. Storage and Use of Supplies				
a. Clean and sterile supplies and equipment are stored appropriately.	Clean and sterile supplies must be stored in a manner to prevent contamination. Bins used to store items must be clean upon inspection. Sterile supplies and instruments that are set-up ahead of time should be protected from contamination and tampering.			
b. Patient care supplies stored at least 36” from a sink or there is a protective barrier (splash guard) to prevent splash contamination; storage under sinks is discouraged except for the following allowed items: clean sharps containers, clean trash bags, detergents, cleaning agents (NO hand soaps), and battery recycle buckets.	To prevent water damage and/or contamination, only chemicals and reagents that do not react with each other or with water can be stored under sinks. On the countertop, all items should be an adequate distance from the sink or there should be a splash guard installed next to the sink.			
c. Supplies stored on shelves and off floors.	Must be 8” off floor.			

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	Must be 18” below sprinkler heads and 5” from ceiling if no sprinklers.			
	Items should be removed from shipping cartons before storage to prevent contamination with soil/debris that might be on the cartons.			
	Outer shipping boxes should not be left in clinical areas due to risk of environmental contamination.			
	Supplies should be stored in plastic, washable containers; storage in cardboard is discouraged.			
d. Supplies are within expiration date.	Sterile items must be clean, within date and properly stored. There should be no open steri-strips or opened packing strip bottles. These items are for single patient use.			
	Supplies should be stocked and rotated “first in, first out” so oldest items are used first.			
e. There is clear separation of clean and dirty activities.	Clean items/areas are clearly separated from dirty items.			
	Need either separate clean/dirty rooms or the designated utility room must flow from clean to dirty.			
f. Items labeled as "single use only" (SUDs) are not reused.	The policy follows the FDA labeled guidelines that prohibit the reuse of Single Use Devices (SUDs). If single use devices are reprocessed, they are sent to the appropriate FDA-approved reprocessing facility. If reprocessed, must have contract available for viewing.			

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10. Risk Analysis				
a. Types of procedures performed and services provided are appropriate for the physical space of the site as well as for the skill level and competency of staff.	New procedures and equipment are commissioned pursuant to Infection Control consultation where appropriate.			
	New construction or renovations are conducted in compliance with Infection Control standards as set forth in the facility's IC plan.			
11. Safe Injection Practices				
ONE NEEDLE: ONE SYRINGE: ONE PATIENT: ONE TIME				
a. Single dose vials are never used as multidose vials.	Single dose vials should be used whenever possible and discarded immediately after use; comply with USP, CDC, CMS and institutional policy regarding safe injection practices and medication preparation.			
5. Linens				
a. Linens are stored appropriately.	Clean linen must be stored in designated area to prevent contamination from traffic and to reduce risk of linen falling on floor.			
	Clean linen must be kept covered if not in a closet, drawer, or cabinet. Linens are laundered according to linen service policy.			
	Exam tables, recliners and short-term use beds should be cleaned weekly, when visibly soiled, and after use for patients requiring Contact Precautions.			

References: CDC 2008, AORN 2014, AAMI 2010, SGNA 2013, ASGE 2011