ASC Quality Collaboration

Sterilization and High-Level Disinfection: What CMS Surveyors Are Looking For

CMS surveyors use a worksheet to assess infection control practices during ASC surveys. The section of the worksheet used to assess practices related to sterilization and high-level disinfection is reproduced below. **Because this the SAME TOOL a CMS surveyor will use to assess these infection control practices, it is also a useful SELF-ASSESSMENT tool for an ASC.**

Unless otherwise indicated, a "No" response to any question below will be cited as a deficient practice.

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

STERILIZATION

A. Critical equipment is sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Are sterilization procedures performed on-site? **(If NO, skip to "F")** (A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
a. **If YES to B**, please indicate method of sterilization:	○ Steam autoclave ○ Peracetic acid ○ Other (please print): _____	
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. A chemical indicator is placed in each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

c. A biologic indicator is performed at least weekly and with all implantable loads	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
H. Additional breaches in sterilization practices not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please print and limit comments to the space provided)**	

HIGH-LEVEL DISINFECTION

Practices to be Assessed	**Was Practice Performed?**	**Manner of Confirmation**
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

a. **If answer to B was YES**, please indicate method of high-level disinfection:	○ Manual ○ Automated ○ Other (please print):		
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
b. High-level disinfection equipment is maintained according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
c. Chemicals used for high-level disinfection are:			
I. Prepared according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
II. Tested for appropriate concentration according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
III. Replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
IV. Documented to have been prepared and replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
d. Instruments requiring high-level disinfection are:			
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions on evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both	
E. Items that undergo high-level disinfection are allowed to dry before use	○ Yes ○ No	○ Observation ○ Interview	

	○ N/A	○ Both
F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Additional breaches in high-level disinfection practices, not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: **(please print and limit comments to the space provided)**	