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 *performing* equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

STERILIZATION		
A. Critical equipment is sterilized	○ Yes ○ No	
B. Are sterilization procedures performed on-site? **(If NO, skip to "F")**	○ Yes ○ No	
(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)		
a. **If YES to B**, please indicate method of sterilization:	○ Steam autoclave ○ Peracetic acid ○ Other (please specify):	

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
C. Items are pre-cleaned according to manufacturer's instructions or, *if the manufacturer does not provide instructions,* evidence-based guidelines prior to sterilization	○ Yes ○ No ○ *Unable to observe*	
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	○ Yes ○ No ○ *Unable to observe*	
b. A chemical indicator *(process indicator)* is placed *correctly, as described in manufacturer's instructions for use, in the instrument packs* in *every* load.	○ Yes ○ No ○ *Unable to observe*	
c. A biological indicator is *used* at least weekly *for each sterilizer and with every load containing* implantable *items, as evidenced by ASC documentation (i.e., log).*	○ Yes ○ No ○ *Unable to observe*	
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	○ Yes ○ No ○ *Unable to observe*	
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	○ Yes ○ No	
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	○ Yes ○ No ○ *Unable to observe*	
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	○ Yes ○ No	
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	○ Yes ○ No	
H. Is immediate-use steam sterilization (IUSS) performed on-site? ***If NO, skip to "High Level Disinfection Section"*** ***If YES, you must also assess the practices at questions "I - K":*** *(A "No" answer does not result in a citation)*	○ *Yes* ○ *No*	

I. If IUSS is performed, all of the following criteria are met:

- *Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization.*
- *Once clean, the item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers' instructions for use for the device, container, and sterilizer.*
- *The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic) that are approved for the cycle being used.*
- *The processed item must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, the sterile field in an ongoing surgical procedure.*

Note: "Immediate use" is defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. IUSS is not equivalent to "short cycle" sterilization performed in accordance with manufacturers' IFUs. IUSS must not be a routine or frequent practice in the ASC.

- ○ *Yes*
- ○ *No*
- ○ *Unable to observe*
- ○ *N/A*

J. Immediate-use steam sterilization is NOT performed on the following devices:

- *Implants.*
- *Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders.*
- *Devices that have not been validated with the specific cycle employed.*
- *Single-use devices that are sold sterile.*

- ○ *Yes*
- ○ *No*

K. Is IUSS performed on a routine basis?

*(A "Yes" answer **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

- ○ *Yes*
- ○ *No*

HIGH-LEVEL DISINFECTION

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

(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 specify):	
C. Items are pre-cleaned according to manufacturer's instructions or, *if the manufacturer does not provide instructions,* evidence-based guidelines prior to high-level disinfection	○ Yes ○ No ○ *Unable to observe*	
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	○ Yes ○ No ○ *Unable to observe*	
b. High-level disinfection equipment is maintained according to manufacturer instructions	○ Yes ○ No ○ *Unable to observe*	
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	○ Yes ○ No ○ *Unable to observe*	
II. Tested for appropriate concentration according to manufacturer's instructions	○ Yes ○ No ○ *Unable to observe*	

III. Replaced according to manufacturer's instructions	○ Yes ○ No ○ *Unable to observe*
IV. Documented to have been prepared and replaced according to manufacturer's instructions	○ Yes ○ No
d. Instruments requiring high-level disinfection are:	
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or, *if the manufacturer does not provide instructions,* evidence-based guidelines	○ Yes ○ No ○ *Unable to observe*
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions or, *if the manufacturer does not provide instructions,* evidence-based guidelines	○ Yes ○ No ○ *Unable to observe*
E. Items that undergo high-level disinfection are allowed to dry before use	○ Yes ○ No ○ *Unable to observe*
F. Following high-level disinfection, items are *placed* in a designated clean area in a manner to prevent contamination	○ Yes ○ No