

ASC Quality Collaboration

Single-Use Device Reprocessing: 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 reprocessing of single-use devices 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.

III. Single Use Devices, Sterilization, and High Level Disinfection

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).

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	