Voluntary Medical Male Circumcision (VMMC) External Quality Assurance (EQA) **Tool C – Reusable Equipment Reprocessing**

Site Name:_____ Reviewer's Name:_____ Date:_____

This Tool (C) aims to objectively assess:

- Infrastructure and personnel for instrument reprocessing
- Processes for instrument reprocessing
- Monitoring and documentation of adequate sterilization

Reviewer Guidance:

The reviewer will record observations by marking "Y" for Yes (wholly adequate), or "N" for No (not wholly adequate) as noted on the form. In cases where the "N" is checked, the reviewer is asked to explain in the Notes section as appropriate.

Any additional general comments may also be recorded in the Comments/Notes section at the end.

Instrument decontamination is a complicated process; deficiencies in any step may put a client at serious risk for infection. Several key elements are identified for the reviewer as a guide during observations. An indicator may be judged adequate overall, with comments identifying the strongest areas as well as problematic components, even though the overall performance may be within acceptable standards. When judged partially or wholly inadequate (N) overall, the specific component(s) that require change should be identified, as well as affirmation of those elements that are sound.

Please obtain permission from the clinical staff to observe them reprocess instruments. Ideally, the reviewer should directly observe all steps of reprocessing applicable to the site: pre-cleaning, cleaning, sterilization, storage, and transportation (as applicable). Understanding that time constraints may not allow direct observation, an alternative is to have the responsible individual talk through or illustrate the steps.

For each item below, please check the correct box to indicate if the answer to the question is Yes, No, or Not Applicable.				
Leadership	**Y**	**N**	**N/A**	**Notes**
C-1. Leadership – Does the site have an individual identified as the POC for instrument reprocessing?				
C-2. Leadership – Does the POC have record of training/competency in instrument reprocessing (reviewer should visually verify)?				
C-3. Leadership – Does the site have an instrument reprocessing SOP available (reviewer should visually verify)?				
Pre-cleaning	**Y**	**N**	**N/A**	**Notes**
C-4. Pre-cleaning – Were the instruments rinsed or wiped off with a damp gauze to remove gross contamination immediately after the case?				
C-5. Pre-cleaning – Is there a process to flag and communicate instrument problems (e.g. dull scissors or non-locking clamp)?				
C-6. Pre-cleaning – Was prolonged soaking (>10 minutes) avoided?				
C-7. Pre-cleaning – If soaking was used, was the use of saline, chlorine, or disinfectant avoided? (plain water is ok; if a detergent (soap) was added, it should be of a type and concentration approved by the instrument manufacturer; please note that soaking in 0.5% chlorine, a common procedure in the past, should not be done)				
C-8. Pre-cleaning – Were instruments left open (i.e. not clamped shut) during and after pre-cleaning?				
C-9. Pre-cleaning – Were instruments transported from point of use to cleaning area in a leak-proof, puncture-proof container?				
C-10. Pre-cleaning – If instruments required transport to another facility for cleaning, was the transport container covered?				
C-11. Pre-cleaning – Were instruments kept moist the entire time between end of case and cleaning?				
Cleaning (mark N/A if site doesn't do this step)	**Y**	**N**	**N/A**	**Notes**
C-12. Cleaning – Was appropriate PPE (hair cover, eye/mouth protection, impermeable gown, gloves, closed shoes) worn during cleaning?				
C-13. Cleaning – Was a clean basin filled with an appropriate amount of water and detergent to allow immersion of the instruments? (There should be enough water to immerse the instruments. There should also be the right ratio of detergent to water to provide the final manufacturer-recommended concentration)				
C-14. Cleaning – Were the instruments cleaned using a soft (nylon) bristle brush under the surface of the water (to avoid producing aerosols)?				
C-15. Cleaning – Were all hinged instruments opened during cleaning?				

C-16. Cleaning – Were instruments immersed or rinsed thoroughly with clean, soft water to remove all loosened soil and residual detergent? (soft water has salts and minerals removed to prevent deposits and buildup on instruments)				
C-17. Cleaning – Were instruments inspected with a magnifying lens after cleaning, prior to drying, to make sure all visible contamination had been removed?				
C-18. Cleaning – Were instruments air-dried or dried by hand with a clean, non-linting cloth?				
C-19. Cleaning – Was the overall flow of instruments in the cleaning area unidirectional from "dirty" to "clean"				
C-20. Cleaning – If both reusable and single use instruments are used, is there an established way these are distinguished from one another?				
Sterilization (mark N/A if site doesn't do this step)	**Y**	**N**	**N/A**	**Notes**
C-21. Sterilization – Were instruments closely inspected under magnification to ensure no visible contamination prior to packaging?				
C-22. Sterilization – Were instruments checked for proper functioning, and lubricated as necessary to allow free movement at hinges, prior to packaging?				
C-23. Sterilization – Does the site have an established process for replacing non-functioning instruments?				
C-24. Sterilization – Are kits assembled to ensure completeness and standard contents?				
Sterilization – Ask the following questions about packaging instruments for sterilization.				
• **C-25.** Is the packaging material consistent with the autoclave manufacturer's recommendations?				
• **C-26.** Are contents identifiable (either visible or labeled by name)?				
• **C-27.** Does packaging securely enclose items to be sterilized?				
• **C-28.** Does packaging permit delivery of contents without contamination?				
• **C-29.** Does packaging maintain sterility of contents until opened (doesn't easily puncture or allow contamination inside)?				
• **C-30.** Is the packaging tamper-proof and able to seal only once?				
C-31. Sterilization – Does every package have an external chemical indicator? (chemical indicators show when a package has been exposed to one or more variables of the sterilization process such as temperature, pressure, time)				
C-32. Sterilization – Is every package labeled with sterilization date, autoclave number, and load number?				
C-33. Sterilization – Is steam sterilization in use? If yes, answer the following:				
• **C-34.** Are cycle parameters being used consistent with instrument manufacturer's IFU for sterilization?				

• **C-35.** Are cycle parameters (date, autoclave number, load number, cycle start and end times, cycle length, temp, pressure, operator initials, external indicator change) recorded in a logbook?				
• **C-36.** Is the autoclave loaded in a manner to ensure sterilant contact and penetration? (not overloaded, packages away from chamber walls, rigid containers not stacked unless validated by manufacturer for this configuration, steri-peel packages on edge with multiple packages placed paper-to-plastic, non-perforated containers placed on edge)				
• Upon completion, does the operator ensure:				
○ **C-37.** Correct cycle parameters met?				
○ **C-38.** External indicators appropriately changed?				
○ **C-39.** No visible signs of moisture? (no dampness, droplets, or puddles on or within a package)				
○ **C-40.** No visible signs of compromised package integrity?				
○ **C-41.** Cycle number and sterilization date on the packages are correct?				
• **C-42.** Is routine sterilizer efficacy monitoring being performed per manufacturer's recommendations (e.g. biologic indicators, Bowie-Dick test, leak tests)?				
• **C-43.** Are autoclave manufacturer's recommendations for water quality being followed?				
• **C-44.** Are autoclave manufacturer's recommendations for routine maintenance being followed and documented?				
C-45. Sterilization –Was the overall flow of instruments in the sterilization area unidirectional from "non-sterile" to "sterile"?				
C-46. Sterilization –Are all biologic and chemical indicators within their expiration dates?				
C-47. Sterilization –Over the past 6 months, have there been adequate amounts of all necessary reprocessing equipment and supplies without stock-outs?				
External Transportation (mark N/A if site doesn't do this step)	**Y**	**N**	**N/A**	**Notes**
C-48. Transportation – Is the portion of the transport vehicle where instrument containers are placed completely enclosed?				
C-49. Transportation – Are the containers for sterile and non-sterile instruments clearly marked?				
C-50. Transportation – Is a system in place to easily segregate sterile and non-sterile instruments?				
C-51. Transportation – Is a system in place to track movement of instrument kits between sites and know where they are at all times? (for example, to find where all kits sterilized on x date in cycle number y are located; if one kit from a specific				

load is noted to have problems, it will be important to immediately identify all the other kits that were in the same load).				
Additional Comments/Notes:				