



## Quality Improvement Secretariat

Ministry of Health & Family Welfare

[www.qis.gov.bd](http://www.qis.gov.bd)

### Sterilization Audit Checklist

Date: \_\_\_\_\_

Facility: \_\_\_\_\_

#### POINT OF USE – Instrument Preparation & Transport

	Yes	No	NK
1. Are instruments wiped of gross soil with sterile surgical sponges and sterile water?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are lumens irrigated with sterile water throughout the procedure to remove gross soil?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are sharps separated from other instruments and placed into a puncture proof container?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are multi-part instruments opened, disassembled and arranged within their original set?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are hinged instruments kept fully open using stringers, racks and/or instrument pegs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are light instruments placed on top of heavy instruments or placed in separate containers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is pre-soak solution or wet towels being used to keep instruments moist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are instruments contained properly during transport to Decontamination area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are transport containers (e.g. bags, carts and/or containers) labeled biohazard?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Are instruments being transported as soon as possible to prevent blood from drying?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### Decontamination – Facility Design, PPE & Procedures

	Yes	No	NK
1. Is the area separate from clean activities and accessible by a door and pass through window?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is floor, walls, ceiling and work surfaces made of proper materials to withstand frequent cleaning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there negative pressure and a minimum of 10 air exchanges to the outside w/o recirculation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is temperature (60-65°F) and humidity (30-60% RH) controlled and recorded daily?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there an appropriate eye wash station (e.g. hands free and able to flush both eyes)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are the manual cleaning sinks 3 section to allow for soaking, washing and rinsing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Do all personnel wear appropriate PPE and remove PPE properly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is there a proper hand wash station and do personnel wash hands when leaving the area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are instruments sorted upon arrival by their different cleaning instructions for use (IFU)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is detergent type, dilution, water quality/ temperature and brushes per the instrument MFG's IFUs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Are sterilization containers cleaned between use and with proper detergent per the MFG's IFU?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Are ultrasonic cleaners used and for proper time according to the instrument MFG's IFUs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Are all mechanical cleaners being tested, i.e. at least weekly, preferably daily?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Are mechanical cleaners loaded properly to allow for effective cleaning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. If the mechanical cleaners have a printout, is it located on the clean side?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### Prep & Pack – Inspection, Assembly & Packaging

	Yes	No	NK
1. Is every instrument visually inspected for cleanliness and function?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are dirty instruments returned to decontamination for re-cleaning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are cleaning brushes only being used in decontamination area and not the clean assembly area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is compressed, medical grade air available and used to dry instruments, i.e. lumens?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are instrument sets being assembled correctly and in appropriate trays?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are misc. items (e.g. towels, count sheets, tray liners, tape) being used properly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Are paper plastic pouches, wraps and/or containers being used correctly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are packaging materials and container accessories being inspected prior to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are all instrument sets (including loaners) at or below the maximum weight of 25 lbs.?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is there a lot control label placed properly on all packages prior to sterilization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Sterilization – Steam, Low Temperature & QA**

	<u>Yes</u>	<u>No</u>	<u>NK</u>
1. Are steam sterilizers being loaded properly, i.e. light items on top, heavy items on bottom?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are steam sterilizer cycles selected in accordance with instrument MFG's IFUs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are MFG's IFUs readily accessible for personnel who are processing instruments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. When IUSS occurs, is it performed correctly, i.e. approved container, cycle, indicators?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are all instruments and packaging systems used in low temperature processes validated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are terminally processed loads allowed to cool to room temperature before handling?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is each sterilizer cycle printout reviewed and initialed before load removal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Does each sterilization package have an external and internal chemical indicator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are internal CIs located properly, i.e. each level of multiple trays, corners of rigid containers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Are biological indicators (BIs) used daily and with every load containing an implant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Do personnel activate and incubate BIs properly, i.e. MFG's IFU and to national standards?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Is an unprocessed BI from the same lot being incubated daily in each incubator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Are pre-vacuum steam sterilizers tested daily for air removal using a Bowie-Dick type test pack?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Are positive BIs sent to microbiology laboratory for gram staining to protect against false +?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Are all sterilization records complete, accurate and presentable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Sterile Storage & House Keeping**

	<u>Yes</u>	<u>No</u>	<u>NK</u>
1. Are sterile items located in a clean, separate and enclosed storage area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is temperature (75°F max) and humidity (30-70% RH) controlled and recorded daily?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is storage shelving appropriate, i.e. bottom shelves covered, all smooth surfaces, clean?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is ceiling or ceiling tiles made of an appropriate construction (e.g. not particulate-fiber shedding)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are sterile wrapped packages placed flat on storage shelves and not stacked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Does each sterile package have a load label with sterilizer no., load no. and date of processing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is an "event-related" sterility assurance policy being used along with FIFO?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are floors cleaned and disinfected at least daily for all instrument reprocessing areas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Do work surfaces and frequently touch items receive daily for all instrument reprocessing areas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Are walls, equipment, ducts, light fixtures and storage shelves on a routine cleaning schedule?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Management & SPD Training**

	<u>Yes</u>	<u>No</u>	<u>NK</u>
1. Are Policies & Procedures updated to best practices, i.e. loaners, hand hygiene, product recall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there a Soiled Instrument Transport Checklist in place at point of use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there an Instrument Tray Audit program in place to inspect instrument sets for accuracy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are reusable instrument MFG's required to provide a validated IFU before purchase, loan or trial?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Have all sterile processing personnel certified and are CE training records up to date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

IUSS = Immediate Use Steam Sterilization (aka Flash sterilization)

**Comments**


---



---



---



---



---

**Name and Signature**