



Peak<sup>™</sup>

Clinical Outcomes Program

# Process Assessment Tool

Let's get started!

**Welcome to the 3M™ Peak™ Program Process Assessment Tool.**

A tool to evaluate your facility's process and identify improvement opportunities.

Name

Facility

Email

**Proceed to questions**

**1. Does the Central Sterilization (CS) supervisory personnel maintain competency and participate in continuing education?**

Yes

No

Some of the time

# 1. Does the Central Sterilization (CS) supervisory personnel maintain competency and participate in continuing education?

Yes

No

Some of the time

**Per:** AAMI ST79:2017, Section 4.2.1 – *Supervisory personnel: All preparation and sterilization activities, including decontamination, inspection, preparation, packaging, sterilization, storage, and distribution, should be supervised by competent, qualified personnel.*

**Next question**

## 2. Are all CS personnel certified?

Yes

No

Some

## 2. Are all CS personnel certified?

Yes

No

Some

**Per:** AAMI ST79:2017, Section 4.2.2 — *All personnel performing sterile processing activities should be certified within two years of employment and should maintain that certification throughout their employment.*

**Next question**

**3. Are reusable items separated from waste at point-of-use?**

Yes

No

### 3. Are reusable items separated from waste at point-of-use?

Yes

No

**Per:** AAMI ST79:2017, Section 6.2 — *Separation of waste and reusable items at point-of-use: At the point-of-use, a) items should be separated into reusable items, single-use disposable items, and waste categories.*

**Next question**

**4. Are soiled items contained during transportation?**

Yes

No

#### 4. Are soiled items contained during transportation?

Yes

No

**Per:** AAMI ST79:2017, Section 6.4 — *Containment: Contaminated items should be contained during transport from the point-of-use to the decontamination area.*

**Next question**

**5. At the point-of-use, after removal of gross soil and prior to transport, are instruments prepared to prevent organic soil from drying?**

Yes

No

**5. At the point-of-use, after removal of gross soil and prior to transport, are instruments prepared to prevent organic soil from drying?**

Yes

No

**Per:** AAMI ST79:2017, Section 6.3.5 — *Prior to transport, instruments should be prepared in such a way as to prevent organic soils from drying by: placing a towel moistened with water (not saline) over the instrument; placing items inside a package designed to maintain humid conditions; or applying a product designed for pretreatment.*

**Next question**

**6. Is the presoaking solution used according to the manufacturer's IFU, including dilution, temperature, and contact time?**

Yes

No

**6. Is the presoaking solution used according to the manufacturer's IFU, including dilution, temperature, and contact time?**

Yes

No

**Per:** AAMI ST79:2017, Section 7.5.1 — *Presoaking: Following point-of-use cleaning (see 6.3), instruments should be presoaked as soon as possible after use with a product intended to loosen soil.*

**Next question**

**7. Is verification of mechanical cleaning equipment performed (e.g. daily testing of mechanical washers and/or ultrasonic) with the appropriate testing methodology?**

Yes

No

**7. Is verification of mechanical cleaning equipment performed (e.g. daily testing of mechanical washers and/or ultrasonic) with the appropriate testing methodology?**

Yes

No

**Per:** AAMI ST79:2017, Section 13.2 — *Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs.*

**Next question**

**8. Does the decontamination area have handwashing stations?**

Yes

No

## 8. Does the decontamination area have handwashing stations?

Yes

No

**Per:** AAMI ST79:2017, Section 3.3.5.7 — *Handwashing stations (sinks and waterless alcohol-based hand rub dispensers) should be located in or near all areas in which instruments and other devices are decontaminated and prepared for sterilization.*

**Next question**

**9. Is the sterile storage room a dedicated space with access restricted to authorized personnel?**

Yes

No

## 9. Is the sterile storage room a dedicated space with access restricted to authorized personnel?

Yes

No

**Per:** AAMI ST79:2017, Sections 3.3.6.4 and 11.1.1 — *The sterile storage room should be kept clean and dry and used only to store sterile and clean supplies.*

**Next question**

**10. Are emergency eyewash stations (required by OSHA) located within 10 seconds travel time of all chemical usage locations?**

Yes

No

**10. Are emergency eyewash stations (required by OSHA) located within 10 seconds travel time of all chemical usage locations?**

Yes

No

**Per:** AAMI ST79:2017, Section 3.3.7 — *ANSI/ISEA Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a “hands-free, stay open” feature once activated.*

**Next question**

**11. Are instruments cleaned and dried before packaging?**

Yes

No

## 11. Are instruments cleaned and dried before packaging?

Yes

No

**Per:** AAMI ST79:2017, Section 8.2 — *In preparation for sterilization, devices should be: cleaned; dried; inspected for cleanliness, flaws, and damage; assembled; and packaged according to the manufacturer's written IFU.*

**Next question**

**12. Are multi-part instruments disassembled prior to sterilization?**

Yes

No

## 12. Are multi-part instruments disassembled prior to sterilization?

Yes

No

**Per:** AAMI ST79:2017, Section 8.2 — *Instruments comprising more than one part or with sliding pieces or removable parts should be disassembled if it is so specified in the manufacturer's written IFU.*

**Next question**

**13. Are instrument sets prepared in trays large enough to equally distribute the mass?**

Yes

No

### 13. Are instrument sets prepared in trays large enough to equally distribute the mass?

Yes

No

**Per:** AAMI ST79:2017, Section 8.2 — *The instrument tray should be large enough to permit equal distribution of the contents in terms of weight and metal mass.*

**Next question**

**14. Do instrument sets exceed 25 pounds?**

Yes

No

#### 14. Do instrument sets exceed 25 pounds?

Yes

No

**Per:** AAMI ST79:2017, Section 8.2 — *Instrument sets, including the sterile barrier system, should weigh no more than 11 kg (25 lb) (ANSI/AAMI ST77).*

**Next question**

**15. Are rigid containers placed on shelves below absorbent items?**

Yes

No

### 15. Are rigid containers placed on shelves below absorbent items?

Yes

No

**Per:** AAMI ST79:2017, Section 10.1.6 — *Rigid sterilization container systems: Rigid sterilization container systems should be placed on shelves below absorbent items. Containers may be stacked if indicated in the container manufacturer's written IFU.*

**Next question**

**16. Are sterilized items allowed to cool before handling?**

Yes

No

## 16. Are sterilized items allowed to cool before handling?

Yes

No

**Per:** AAMI ST79:2017, Section 10.3.1 — *Terminally sterilized items should be allowed to cool to room temperature before handling. An infrared gun or temperature-sensing device may be used to verify that sterilized items have reached a defined temperature (e.g., 24°C [75°F]). The time allowed for cooling should take into account the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. Items should not be touched during the cooling process.*

**Next question**

**17. Are loads containing implants monitored with a PCD containing a biological indicator (BI) and a Type 5 integrating indicator and are implants quarantined until the BI result is available?**

Yes

No

**17. Are loads containing implants monitored with a PCD containing a biological indicator (BI) and a Type 5 integrating indicator and are implants quarantined until the BI result is available?**

Yes

No

**Per:** AAMI ST79:2017, Section 13.6.3 — *Releasing implants before the BI results are known is unacceptable.*

**Next question**

**18. Is a control BI run each day that test BIs are incubated?**

Yes

No

**18. Is a control BI run each day that test BIs are incubated?**

Yes

No

**Per:** AAMI ST79:2017, Section 13.7.2.4 — *Each day that test BIs are run, at least one BI that is from the same lot should be incubated in each incubator.*

**Next question**

**19. Is a Bowie-Dick test performed each day the dynamic-air-removal steam sterilizers are used?**

Yes

No

**19. Is a Bowie-Dick test performed each day the dynamic-air-removal steam sterilizers are used?**

Yes

No

**Per:** AAMI ST79:2017, Section 13.7.6 — *For dynamic-air-removal sterilizers, a Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load.*

**Next question**

**20. Is Bowie-Dick Testing done daily in prevacuum sterilizers before first processed load?**

Yes

No

## 20. Is Bowie-Dick Testing done daily in prevacuum sterilizers before first processed load?

Yes

No

**Per:** AAMI ST79:2017, Section 13.7.6.1 — *A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load.*

**Next question**

**21. What Type of Chemical Indicator are you using for internal pack monitoring for steam sterilization?**

Type 4

Type 5

Type 6

## 21. What Type of Chemical Indicator are you using for internal pack monitoring for steam sterilization?

Type 4

Type 5

Type 6

**Per:** AAMI ST79:2017, Section 13.5.2.2.2 — *One or more internal chemical indicators should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters.*

**Next question**

**22. Is documentation for each mechanical washer being maintained (e.g. digital readouts, cycle printouts)?**

Yes

No

## 22. Is documentation for each mechanical washer being maintained (e.g. digital readouts, cycle printouts)?

Yes

No

**Per:** AAMI ST79:2017, Section 13.2 — *Monitoring and verification of cleaning processes should be documented. Some mechanical washers have digital readouts and cycle printouts that should be reviewed for each cycle and initialed by the operator to indicate an acceptable cycle. Cycle printouts or cycle recording devices should be located on the clean side of pass-through mechanical washers.*

**Next question**

**23. For each steam sterilization cycle is the following being recorded?**

- The load number
- The specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets)
- The exposure time and temperature, if not provided on the sterilizer recording chart
- Operator identification
- The results of biological testing, if applicable
- The results of Bowie-Dick testing, if applicable
- The response of the CI placed in the PCD, if applicable
- Any reports of inconclusive or nonresponsive CIs found later in the processed devices

Yes

No

**23. For each steam sterilization cycle is the following being recorded?**

- The load number
- The specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets)
- The exposure time and temperature, if not provided on the sterilizer recording chart
- Operator identification
- The results of biological testing, if applicable
- The results of Bowie-Dick testing, if applicable
- The response of the CI placed in the PCD, if applicable
- Any reports of inconclusive or nonresponsive CIs found later in the processed devices

Yes

No

**Per:** AAMI ST79:2017, Section 13.3.3 — For each sterilization cycle, the following information should be recorded: the load number; the specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets); the exposure time and temperature, if not provided on the sterilizer recording chart; operator identification; the results of biological testing, if applicable; the results of Bowie-Dick testing, if applicable; the response of the CI placed in the PCD, if applicable; and any reports of inconclusive or nonresponsive CIs found later in the processed devices (see also 13.5.2.2).

**Next question**

**24. Are outside shipping containers and corrugated cartons present in sterile processing area?**

Yes

No

## 24. Are outside shipping containers and corrugated cartons present in sterile processing area?

Yes

No

**Per:** AAMI ST79:2017, Section 3.3.6.5 — *A breakout area/room should be located near or adjacent to a surgical or supply processing department. The purpose of this area/room is to remove items from external shipping cartons, as shipping cartons can harbor and transport dust and debris that should not enter a sterile processing department.*

**Next question**

**25. Do shelving and storage carts have a physical barrier between the bottom shelf and the floor?**

Yes

No

## 25. Do shelving and storage carts have a physical barrier between the bottom shelf and the floor?

Yes

No

**Per:** AAMI ST79:2017, Section 11.1.1 — *Sterile items should be: stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes; stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls; stored in such a way that wrapped packages are not stored beneath rigid sterilization containers on the same shelf; and positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.*

**Next question**

**26. Are devices containing lumens only sterilized in specific VH2O2 sterilizers with specific VH2O2 cycles?**

Yes

No

## 26. Are devices containing lumens only sterilized in specific VH2O2 sterilizers with specific VH2O2 cycles?

Yes

No

**Per:** AAMI ST58, Annex H.3c — *The only lumened items that should be sterilized are those with lumen sizes cleared by the FDA for the specific hydrogen peroxide gas sterilizer being used. FDA-cleared lumen internal diameter and length vary among manufacturers and sterilizer models. The cycles, times and characteristics also vary among manufacturers. The user should consult the sterilizer manufacturer's written IFU to identify specific items appropriate for sterilization in the specific sterilizer cycle.*

**Next question**

**27. For each cycle, is the facility documenting: assigned lot number (including sterilizer and cycle number); date and time of cycle; specific load contents; exposure time/temp if not provided on sterilizer chart; name/initials of operator; results of BI test; and any reports of inconclusive or nonresponsive CIs?**

Yes

No

**27. For each cycle, is the facility documenting: assigned lot number (including sterilizer and cycle number); date and time of cycle; specific load contents; exposure time/temp if not provided on sterilizer chart; name/initials of operator; results of BI test; and any reports of inconclusive or nonresponsive CIs?**

Yes

No

**Per:** AAMI ST58:2013, Section 9.2.2 — *For each chemical sterilization or high-level disinfection cycle, the following information should be recorded and maintained: the assigned lot number, including chemical sterilizer, processor, or soaking container identification and cycle number; the specific contents of the lot or load, including quantity, department, and a description of the items; the exposure time and temperature, if not provided on the physical monitors; the date and time of cycle; the time, temperature, and—if applicable—chemical concentration of the exposure phase of the chemical sterilization or high-level disinfection cycle; the name or initials of the operator; the results of BI or spore strip testing, if applicable; and any reports of inconclusive or nonresponsive CIs or low MRC or MEC testing results (as indicated by solution test strips or chemical monitoring devices).*

**Next question**

**28. What is your frequency for routine sterilizer efficacy testing with a BI PCD?**

Weekly

Daily

Daily + Implants

Every Load

## 28. What is your frequency for routine sterilizer efficacy testing with a BI PCD?

Weekly

Per: AAMI ST79:2017, Section 13.6.1 — *A BI PCD should be used at least weekly and preferably daily.*

Daily

Daily + Implants

Every Load

**Next question**

**29. What is the current frequency of BI monitoring practice for VH2O2?**

Weekly

Daily

Daily for each cycle type

Every Load

## 29. What is the current frequency of BI monitoring practice for VH2O2?

Weekly

Daily

Daily for each cycle type

Every Load

**Per:** AAMI ST58:2013, Section 9.5.4.3 — *A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle (see 9.5.4.5). Each load containing implantable devices should be monitored and, whenever possible, quarantined until the results of the BI testing are available.*

**Next question**

**30. What is the current frequency of BI monitoring practice for EO?**

Weekly

Daily

Daily + Implants

Every Load

Not applicable

### 30. What is the current frequency of BI monitoring practice for EO?

Weekly

Daily

Daily + Implants

Every Load

Not applicable

**Per:** AAMI ST41:2008 (R) 2018, Section 10.6.1 — *A BI PCD should be used in every load.*

**Continue to ATP Assessment**

The ATP Assessment will test the CLEAN SIDE within your Central Sterile Services Department.

Please swab each touchpoint and record your results below.

**Case Cart Swab Touchpoint**

Results

**Work Station Swab Touchpoint**

Results

**Continue with swab touchpoints**

**Door Handle Swab Touchpoint**

Results

**Light Switch Swab Touchpoint**

Results

**Phone Swab Touchpoint**

Results

**Surgical Instrument Touchpoint**

Results

**Continue with swab touchpoints**

**Bottom Shelf of Sterile Storage Touchpoint**

Results

**Computer Keyboard Touchpoint**

Results

**Computer Mouse Touchpoint**

Results

**RANDOM - User chooses**

Results

**Complete Assessment**

**Thank you for completing the 3M™ Peak™ Program Process Assessment Tool.**

Please **SAVE** this PDF using the recommended file naming convention:

**Last Name\_Process Assessment\_Date.pdf.**

Once saved, please review the results with your Central Sterilization Manager.

Section Results

/ 2

Personnel Considerations

/ 5

Cleaning and Decontamination Process

/ 3

Facility Design

/ 4

Instrument Inspection, Preparation and Packaging

/ 7

Steam Sterilizers and Monitoring

/ 2

Documentation

/ 2

Sterile Storage and Distribution

/ 2

VH2O2 Sterilizers and Monitoring

/ 3

BI Frequency Monitoring

Total Results

/ 30

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