

# Monitoring the Effectiveness of the Sterilization Process

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**\*\*This in-service has been Approved by the CBSPD, Inc. for 1 CEU.**

Today there are many choices for sterilization in the healthcare facility:

- Saturated steam under pressure
- Ethylene oxide gas
- Low Temperature gas plasma
- Peracetic Acid
- Dry Heat
- Ozone

Regardless of the sterilization method the sterile processing technician **must follow the device manufacturer's instructions**. These should be obtained and saved where they can be referenced each time the device is processed.

This in-service will focus on monitoring the process of sterilization. Steam should always be the preferred method of sterilization unless otherwise directed by the manufacturer of the device. In addition, the technician should always follow the sterilizer manufacturer's directions for operating the sterilizer. Sterilization equipment should not be used unless the technician is competent in its use.

There are three types of monitoring performed for sterilization; administrative, chemical and biological. Administrative monitoring is making sure all policies and procedures for sterilization are followed by all personnel each and every time. Chemical monitoring is the use of chemical indicators and tape to identify problems with the process. Biological monitors (or indicators) are used as the test to verify that all conditions for sterilization were met. Let's look at each of these separately:

***Physical monitoring*** includes time, temperature and pressure-recording devices and gauges. Most sterilizers today have printouts that document the cycle temperature, pressure and time. The sterilizer operator should label charts/printouts with the sterilizer number and date. (NOTE: Most facilities have more than one sterilizer; they should be numbered to easily identify the suspect sterilizer if a problem occurs). At end of each cycle, **and before items are removed**, the sterilizer operator must examine the chart or printout and verify that all the parameters were met. Verification should be in the form of initialing the record.

***Chemical Monitors*** - (also called *chemical indicators or CIs*) (SEE PHOTO) should be used with each package (inside and outside). They are designed to detect problems associated

with incorrect packaging, incorrect loading or malfunction. So, they play an important role in quality assurance of each item and load. However, CIs are not a sterility test. It is important to read the CI manufacturer's instructions to verify that the CIs being used were designed for the cycles used (wrapped cycles vs. flash cycles for steam; ethylene oxide gas (100% or mixtures), low temperature gas plasma, dry heat, peracetic acid or ozone). It is also important to know how to use, store and interpret the CIs.

CIs have been classified by the FDA into five classes depending on their action.

*Class I* indicators are process indicators. They are intended to be used with individual items to demonstrate that the items have been exposed to the sterilization process and to distinguish between processed and unprocessed packs. An example is autoclave tape.

*Class II* indicators are special test CIs such as the dynamic air removal test (formerly called the Bowie-Dick test).

*Class III* indicators are single parameter indicators. This means they measure only one of the parameters of the sterilization process.

*Class IV* indicators are multi-parameter indicators. With these indicators, they reveal a change in one or more predefined process parameters based upon a chemical or physical change resulting from exposure to a process. Therefore, they provide much more information about the sterilization cycle than a Class III indicator.

*Class V indicators* are known as chemical integrators. These are designed to react to all of the critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the relevant biological under the labeled conditions of use. This means that integrators closely resemble a biological. However, it is important to understand that chemical integrators do not contain spores and therefore cannot be substituted for a biological.

***Dynamic Air Removal Test - DAR (formerly called The Bowie-Dick test)*** is required daily for all pre-vacuum steam sterilizers. This is not a sterility test; it only tests the ability of the sterilizer's *mechanical* air removal system to remove air from the chamber. Always follow the test pack manufacturers' instructions for use, storage and interpretation of the results. If the steam is turned off at night, the DAR test should be performed the first cycle of the day (note: some sterilizer manufacturers recommend a warm-up cycle be run first). If the sterilizers stay on 24-hours a day, the DAR test should be performed the same time every day. Most facilities use a pre-made DAR test purchased from an outside company. However, you can make your own DAR test pack following AAMI Guidelines. Placement of the DAR pack is essential. The recommended location is on the bottom shelf over the drain line. This spot is the coldest location in the sterilizer and therefore represents the greatest challenge. The DAR test must be performed under specific conditions. Unless otherwise directed by the manufacturer of the DAR test, the test should be run for 3 ½ to 4 minutes with no dry time. There should be nothing else in the sterilizer. No other test should be performed along with the DAR test. At the end of the

cycle, the door should be opened and the cart with the pack removed. The cart should **not** remain inside the sterilizer to cool down. After cooling, the pack should be opened and the results reviewed. There should be a complete and even color change of the indicator sheet. Any incomplete or inconclusive results should immediately be reported to the supervisor and the test repeated. If the second test fails, the sterilizer should not be used and a service call placed.

**Biological Monitors** – include biological indicators (vials) and biological test packs now called process challenge devices (PCDs). Always follow the BI manufacturer's instructions for storage, expiration date, cycles it can be used to monitor (not all BIs can be used on all types of cycles), how to follow-up after sterilization (e.g. incubation) and how to interpret the results. Biological indicators (BIs) are intended to demonstrate whether or not the conditions in the sterilizer were adequate to achieve sterilization. However, a negative BI does not prove that all items in the load were sterile or all exposed to adequate sterilization conditions. It is important to use the BIs for the type of cycles or sterilization process you are testing: For example:

- Steam cycles are tested with the spore *geo bacillus stearothermophilus*
- Ethylene oxide gas cycles are tested with the spore *bacillus atrophaeus*
- Low temperature gas plasma cycles are tested with the spore *geo bacillus stearothermophilus*
- Dry heat cycles are tested with the spore *bacillus atrophaeus*
- Peracetic acid cycles are tested with the spore *geo bacillus stearothermophilus*
- Ozone cycles are tested with the spore *geo bacillus stearothermophilus*

It is important to obtain the BI manufacturer's instructions for use, storage, handling and incubation. Different spores require different incubation temperatures; *geo bacillus stearothermophilus* is a heat loving spore and requires a temperature of 55-60°C to grow. *bacillus atrophaeus* only requires body temperature (35-37°C) to grow. The conventional BIs (those requiring incubation) need 48 hours to get a final reading (exception is the BI test for peracetic acid which requires 7 full days for a final readout).

Today, there is one manufacturer which has a "rapid" spore test providing a final result for steam cycles in three hours (wrapped loads) and one hour (unwrapped [flash] cycle). There is also a new BI for peracetic acid which gives a final result in 24 hours. If an incubator is used to incubate the BI, verify the temperature of incubator routinely and document the document results. Otherwise follow the BI manufacturer's instructions for using the "auto reader" for the rapid results.

Most facilities today use a pre-made process challenge device (PCD). If a PCD is not provided, follow the sterilizer manufacturer's instructions for construction of their recommended PCD which will represent the greatest challenge to the sterilizer. If you choose to make your own, make sure it complies with AAMI recommendations for PCDs.

Placement of the PCD in the load is critical to present the greatest challenge to the sterilizer to remove air and get the sterilant into the BI vial. The recommended location for the PCD is dependent upon the method of sterilization:

- Steam - over the drain line, bottom shelf (coldest spot)
- Ethylene oxide gas (center of the load; however in larger sterilizers multiple PCDs may be recommended in several locations throughout the load)
- Low temperature gas plasma - bottom shelf, back of sterilizer

**Frequency** of use. Depending on the sterilization method, the frequency of BI monitoring differs. The following is recommended for routine BI monitoring:

- Steam - at least weekly; preferably daily. With all loads containing implantable devices (the BI test pack must also contain a Class V chemical integrator). All implantable devices should be quarantined until BI results known. Should be performed in the first working load of the day after the DAR test. (NOTE: When running a gravity displacement cycle, a BI must be included in the load since this cycle is not routinely BI tested)
- Ethylene oxide gas - with each load/cycle.
- Low temperature gas plasma - first load of the day.
- Peracetic acid - daily.
- Dry heat - each cycle
- Ozone - daily

In addition to routine BI monitoring, there are other times when the sterilization equipment needs to be tested. It is recommended that your sterilizer be re-tested;

- 1) after any major repair (not including routine maintenance)
- 2) Installation of a new sterilizer installation or relocation of an existing one

This testing is somewhat different than the routine testing. In this testing three consecutive PCD tests are performed in an otherwise empty sterilizer. NOTE: For a pre-vacuum steam sterilizer, three consecutive BI tests of the gravity displacement cycle must be performed. These tests (pre-vacuum and gravity) tests are then followed by three consecutive DAR tests. All tests must be negative before the sterilizer can be put back into use. You will note that this process reverses the usual method of testing however, this is the required procedure.

**Use of Controls** - Control BI is needed to verify the pre-sterilization viability of the spores. It is important to always verify that the lot number from the BI vial or test pack is from the same lot number as the control vial or the test is considered not valid.

You should document the lot numbers on your records. Used BI and control vials are usually discarded in biohazardous trash however check with your Infection Control Department where you should discard them after use.

**Documentation** - It has been said that no job is complete until the paper work is done. Nothing is truer when it comes to sterilization. One of the most important parts of the

documentation process is known as *lot control*. This is where a special identification system is used to identify each item placed in each load. If there is a sterilization failure; the items can be tracked back to the specific sterilizer and load for recall. Usually, facilities use a label with a "gun". The user dials in the specific numbers. At a minimum, the label should identify the sterilizer number, load/cycle number and date the item was sterilized. If the facility is still using expiration dates, then the date the item was sterilized is expressed as a Julian date (actual number of the day of the year) and the expiration date is noted. However, most facilities today use event related dating therefore, no expiration date is needed. However what is **needed** on the label, is a statement that the "item will remain sterile until the package is compromised" or similar statement. It is important for the sterile processing technician to carefully review the lot control information for each sterilization cycle to make sure all information is correct or items may not be recalled if necessary.

Documentation of the BI test results is also very important. The test result should be read at the time indicated by the manufacturer (48 hours for a conventional BI, 3 hours for the rapid BI and one hour for the rapid Flash BI). Also document the control vial results and the lot number of the control vial and rest vial to prove they were from the same lot number.

All phases of the sterilization process should be documented. Usually, a Sterilization Log form is used to record all items processed and a BI record book is used to document all BI testing. The documentation needed (minimum) is:

- Sterilizer number, date and time load started.
- Sterilizer operator name
- Results of DAR test
- Items processed in each load; records should be specific indicating the department (e.g. OR), name of device (e.g. Major Set # 2) and quantity of each device)
- The temperature, exposure time and dry time selected
- If a test pack or BI test pack was included in the load (list with load contents).
- Printout for the cycle; signed by the sterilizer operator.
- BI test documentation including when the BI was placed in the incubator or auto reader; time the results were read; lot number for BI vial and control vial; results of BI vial and control vial; name of person placing the BI test in the incubator/auto reader; name of person providing the final reading of the BI.

Sterilization log forms should be kept neat and legible. If items need to be recalled and the writing is not legible, items can be missed. If a mistake is made, whiteout should not be used; instead draw a line through the error and note "error".

*Recalls* – So, what happens when there is a positive BI? When positive BI occurs, all items processed since the last known negative test must be considered non-sterile, retrieved, if

possible and re-processed. The facility should have a Recall Policy developed in the event of a recall and Infection Control should be part of the process in its development. The policy should also address follow-up of patients for recalled items.

Follow the BI manufacturers instructions for positive BI follow-up; some recommend sending the positive BI vial to the lab to check for the bacillus organism. All items retrieved should be documented on the Sterilization log form (usually a line is drawn through the affected items on the log) and any items not retrieved should be identified (circled). All items retrieved must be completely reprocessed.

**SUMMARY:** Sterilization represents a major responsibility of the sterile processing technician. All policies and procedures must be followed each and every time; all processes documented and all records kept neat and legible. Sterilization records can be subpoenaed in a court of law therefore the records should reflect organization not chaos.

#### **QUIZ ON MONITORING THE EFFECTIVENESS OF THE STERILIZATION PROCESS:**

**This in-service is Approved by the CBSPD for 1 CEU. Complete this post test and follow the directions at the end of the test for payment and results.**

Match the spore used for each type of sterilization process:

- |                                     |                                       |
|-------------------------------------|---------------------------------------|
| 1. _____ Ethylene oxide gas         | A. Bacillus subtilis                  |
| 2. _____ Steam                      | B. Bacillus atrophaeus                |
| 3. _____ Low temperature gas plasma | C. geo bacillus<br>stearothermophilus |
| 4. _____ Dry Heat                   | D. bacillus<br>stearothermophilus     |
| 5. _____ Ozone                      |                                       |
| 6. _____ Peracetic acid             |                                       |
7. The test performed to verify the air removal process on pre-vacuum steam sterilizers is known as the
- A) Pressure test
  - B) Bowie-Dick test
  - C) Dynamic Air Removal test
  - D) Spore test

8. The method used to track devices in each load and sterilizer is called:
  - A) Documentation
  - B) Tracking
  - C) Recall
  - D) Lot control
9. Test packs and DAR tests should be placed in what location in the steam sterilizer?
  - A) top front
  - B) top back
  - C) bottom front
  - D) bottom back
10. A chemical integrator is listed as which class of indicators?
  - A) Class V
  - B) Class IV
  - C) Class III
  - D) Class II
11. After a major repair, what is the testing required before placing a steam sterilizer back into use?
  - A) a DAR test followed by a BI
  - B) 3 DAR tests followed by 3 BI s
  - C) a BI followed by a DAR test
  - D) 3 BI s followed by 3 DAR tests
12. Interpretation of a sterilizer printout is an example of which type of monitoring?
  - A) Physical
  - B) Administrative
  - C) Chemical
  - D) Biological
13. Control vials for BI tests should
  - A) be read weekly
  - B) have the same lot number as the BI test
  - C) be used monthly
  - D) be discarded in with the regular trash
14. A process challenge device for steam cycles must be used
  - A) Daily
  - B) Monthly
  - C) Weekly
  - D) Twice a week
15. Process challenge devices for ethylene oxide should be used
  - A) Daily
  - B) With each cycle/load
  - C) Weekly
  - D) Monthly

## Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

**No refunds (all sales are FINAL), prices subject to change.**

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.  
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

**Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.**

Name: \_\_\_\_\_

Mail to:  Home  Work

Full Address: \_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

For Credit Card Orders Only:  Visa  MasterCard  Discover

Credit Card Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Person's Name on Card: \_\_\_\_\_

Card Billing Address: \_\_\_\_\_

\_\_\_\_\_

If you have any questions, please email [heidi@spdceus.com](mailto:heidi@spdceus.com)

Thank you!