STANDARD OPERATING PROCEDURES

DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

TITLE:	**Monitoring Autoclave Efficacy Using Biological Indicators**
SCOPE:	Animal Care Personnel
RESPONSIBILITY:	Facility Manager and Technical Staff
PURPOSE:	To Outline the Proper Procedures for Assessing Autoclave Efficacy Using Biological Indicators

I. PURPOSE

1. Biological Indicators (BI) are used for monitoring the efficacy of saturated steam sterilization processes in all facility autoclaves.

II. RESPONSIBILITY

1. The Facility Manager ensures technical staff is trained in the correct usage of BI.

2. The Facility Manager, or their designee, monitors the efficacy of autoclave sterilization by the use of BI weekly, or with each load, if autoclaves are not used weekly.

III. PROCEDURE

1. BI steam test packs are single-use, pre-assembled test packs. Each test pack contains a BI and a chemical steam indicator and are used to monitor the effectiveness of common steam sterilizing processes, including 250^0F & 270^0F (121^0C & 132^0C) gravity and pre-vacuum cycles.

2. BI steam test packs are designed to provide resistance to steam sterilization, making it suitable for use as a process challenge device that exhibits the same biological resistance as an Association for the Advancement of Medical Instrumentation (AAMI) steam test pack.

3. Place a steam test pack (e.g., Steris Verify® or SPS Medical SporView® Plus) in a fully loaded autoclave chamber. **Position the test pack toward the front/bottom of the chamber and near the drain**.

4. Process the load using the appropriate sterilization cycle.

5. After sterilization processing has been completed, allow items to cool until safe to handle. Remove the test pack from the autoclave and allow to cool. Observe the chemical indicator strip visible through the clear portion of the Verify® test pack or the chemical indicator on the outside of the Sporview®

test pack for evidence of steam exposure. The chemical indicator turns brown upon exposure to steam. If the chemical process exposure indicator is unchanged, exposure to the sterilization process may not have occurred, sterilization procedures are reviewed, the test repeated, and an entry is made on the ***Equipment Log Sheet*** in the ***Autoclave Log Book***. If the indicator fails after the second attempt, the Facility Manager is notified, sterilization procedures are reviewed, and an entry is made to the ***Equipment Log Sheet*** stating the problem, the corrective action is taken, and resolution is achieved.

6. If the chemical indicator did change to brown, remove the BI and label with date, load, and autoclave ID.

7. Firmly seal the Verify® BI by following the recommended technique shown in figures 1 and 2 of the manufacturer's instruction pamphlet. The indicator cap is properly sealed when the cap is pushed down to the second black bar on the vial label. Although the Verify® Activator is not essential for sealing, its use is recommended to assure the best and most consistent vial sealing.

8. If the BI is not going to be incubated soon after activation, it is recommended that it not be activated, but kept in the sealed condition at room temperature.

9. To activate the BI, crush the inner vial by using the appropriate activator. The BI is properly activated when the growth medium is released from the inner crushed ampoule and is in contact with the spore disc. It is not necessary to shake or invert the activated BI after removal from the activation.

10. Place the activated BI vial in the incubator. The incubator contains a dry heating block for incubation at 55-59^0 C. **A positive control shall be run once a month**, concurrently when a BI is incubated, to validate the test result. **This is accomplished by incubating a non-sterilized BI of the same lot number as the test vial**. Seal and activate the control BI as described in steps 7-9 above. Place the control in the same incubator as the test indicator. The non-sterilized positive control should indicate growth within 24 hours by a change in the color of the medium from a clear deep blue to turbid yellow. The incubator is equipped with a blinking red light on the top indicating that the correct temperature is achieved for incubation.

11. **Check the BI the morning after, and at 24 hours, for test results**. If sterilization of the indicator was achieved, the test indicator will show no color change during the incubation period, i.e., there will be no turbidity, and the growth medium will remain deep blue. Indicator vials contain adequate growth medium for incubation up to seven days if desired. Incubating beyond seven days is not recommended. If a positive test indicator is observed, sterilization procedures are reviewed, the test repeated, and an entry is made on the ***Equipment Log Sheet*** in the ***Autoclave Log Book***. If the indicator fails after the second attempt, the Facility Manager is notified, sterilization procedures are reviewed, and an entry is made to the ***Equipment Log Sheet*** stating the problem; the corrective action is taken and the resolution achieved.

12. Record results in the ***Autoclave Sterilization Record***. If the indicator failed to turn, be sure to describe in the ***Equipment Log Sheet*** steps taken to identify the improperly sterilized load and resolve the lack of complete sterilization. Adjustments should be made and tests rerun until the problem is resolved.

13. Following incubation, dispose of processed indicators as you would other trash. Each package of indicators has an expiration date on the bottom. Be sure to use only in-date vials.

IV. SAFETY CONSIDERATIONS

1. Care should be taken when removing a BI from autoclaves/test packs, as they can be hot. Let indicators cool before removing.

2. Heat resistant autoclave gloves should be worn whenever removing hot items from the autoclave.

3. A properly operating autoclave is essential for safety. Perceived problems should be reported to the Facility Manager immediately for corrective action.

V. DOCUMENTATION REQUIRED

1. Autoclave Sterilization Record

VI. REFERENCES

1. STERIS VERIFY® Steam Test Pack Biological Indicator instruction pamphlet.

2. SPS Medical SporView® Plus Steam BI Test Pack Pamphlet

Approved: **Date:**