STANDARD OPERATING PROCEDURES

DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

Association for the Advancement of Medical Instrumentation (AAMI) steam test pack.

8. Weekly, or with each load if autoclave is used less than weekly, a steam test pack is placed toward the front/bottom of the chamber near the drain, in accordance with ***SOP# 1007 Verify Steam Test Packs/Self Contained Biological Indicators***. Results are recorded in the ***Autoclave Sterilization Record***. If after processing and incubation the contents of the vial(s) **changes color (i.e., turns from blue to yellow), sterilization was not achieved**. The autoclave operation should be reviewed and if working properly, times should then be increased by increments of 5 minutes and another sample should be taken. If the indicator fails to change, an entry is made on the ***Equipment Log Sheet*** in the ***Autoclave Log Book***, and the Facility Manager is notified for corrective action.

9. Weekly, or with each load if liquids are autoclaved less than weekly, a MagnaAmp™ biological indicator is suspended within a liquid filled container (e.g., full water bottle) in an area of the load that is considered the most difficult to sterilize (e.g., within the water bottle located in the middle of the bottle rack) according to ***SOP# 1013 entitled Monitoring Steam Sterilization of Liquids***. Results are recorded in the ***Autoclave Sterilization Record***. If after processing and incubation the contents of the vial(s) changes color, sterilization was not achieved. The autoclave operation should be reviewed and if working properly, times should then be increased by increments of 5 minutes and another sample should be taken. If the indicator fails to change, an entry is made on the ***Equipment Log Sheet*** in the ***Autoclave Log Book***, and the Facility Manager is notified for corrective action.

10. Daily air removal tests are single-use test packs to assess the effectiveness of air removal from pre-vacuum steam autoclaves. The Steris Steraffirm™ Bowie-Dick Test Packs are for use with121^0-124^0C (250^0-255^0F) pre-vacuum sterilizers. The SPS Medical AirView™ Bowie-Dick or Steris DART® test packs are for use with 132^0 to 134^0C (270^0-274^0F) pre-vacuum sterilizers.
    a. After pre-heating the sterilizer by completing a cycle either a AirView™ Bowie-Dick or DART® indicator is placed near the drain of an empty chamber and a test cycle (132^0C/250^0F for 3.5-4 minutes) is chosen from the operating menu.
        1. Upon completion of the cycle the yellow bars at the end of the DART®, indicator should turn black indicating residual air has been removed and allowing complete steam penetration. Snap off the plastic window, slide out the chemical indicator and record the results.
        2. Upon completion of the cycle the process indicator on the outside of the AirView® test pack should be darkened. After allowing test pack to cool the test pack can be opened and test sheet removed to view results. The entire indicator ink figure will change color from yellow to blue/purple if the air removal process was successful.
    b. After pre-heating the sterilizer by completing cycle a Steraffirm™ Bowie-Dick Test Pack is placed near the drain of an empty chamber and the Bowie-Dick Test cycle (121^0 C/250^0 F for 8-8.3 minutes) is

chosen from the operating menu. Upon completion of the cycle the process indicator on the outside of the pack should be darkened. After allowing test pack to cool the test pack can be opened and test sheet removed to view results. The entire indicator ink figure will change color from yellow to blue/purple if the air removal process was successful.

c. If the an air removal indicator fails to change color completely, an entry is made on the ***Equipment Log Sheet*** in the ***Autoclave Log Book***, and the Facility Manager is notified for corrective action.

11. When results of autoclave monitoring are unacceptable, an entry is made on the ***Equipment Log Sheet*** stating the problem, the corrective action taken, and how it was resolved. This record is maintained in the ***Autoclave Log Book***.

12. When autoclave equipment fails to operate properly, an entry is made on the ***Equipment Log Sheet*** stating the problem, the corrective action taken, and how it was resolved. This record is maintained in the ***Autoclave Log Book***.

13. Most autoclave indicators have expiration dates. Autoclave operators should ensure that only in date indicators are used.

14. When autoclaves with the capability to generate printouts or temperature charts are utilized, these records of autoclave function should be reviewed from each load to assure that proper sterilization cycle has occurred. The autoclave operator should make sure paper is in the printer at all times and replaced as needed.

15. Managers identify, date, and retain autoclave-generated printouts and temperature charts for a period of at least 6 months at their facility.

16. Facility Managers retain results of monitoring autoclave sterilization for a period of 6 months***.***

17. When research is being conducted in accord with ***21 CFR Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies*** and autoclave procedures/techniques could directly affect the generation, measurement, or assessment of research data,
    a. Original autoclave monitoring records and printouts are submitted to the testing facility management and Study Director for archival in accordance with ***21 CFR Part 58***.
    b. The facility manager, or designee, makes exact copies of the records.
    c. Exact copies are annotated that they are an exact copy and are signed and dated by the facility manager, or designee.
    d. The exact copies are then retained by the animal facility manager as described in **SOP #010**.