

**STANDARD OPERATING PROCEDURES**  
**DIVISION OF COMPARATIVE MEDICINE**  
**UNIVERSITY OF SOUTH FLORIDA**

SOP#: 1002.9

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<b>TITLE:</b>	<b>Monitoring Autoclave Sterilization</b>
<b>SCOPE:</b>	Animal Care Personnel
<b>RESPONSIBILITY:</b>	Facility Manager and Technical Staff
<b>PURPOSE:</b>	To Outline the Proper Procedures for Monitoring Autoclave Sterilization

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**I. PURPOSE**

1. Autoclaves are located in the USF Health Byrd Alzheimer's Institute, College of Medicine, Interdisciplinary Research Building, and Stabile Research Building animal facilities and used to sterilize caging, water bottles, water, feed, bedding, instruments, equipment and to decontaminate biohazardous materials. In all cases, it is important that complete sterilization is accomplished. This standard operating procedure describes the Division's sterilization monitoring program for assuring proper sterilization.

**II. RESPONSIBILITY**

1. It is the responsibility of the Facility Manager to ensure that autoclaves are appropriately monitored and maintained in good working order.
2. It is the responsibility of the Facility Manager to ensure that all research and technical staff using autoclaves in their facility are adequately trained and experienced in these procedures.
3. The Facility Manager is responsible for maintaining records of the results of autoclave monitoring at the frequency described below, or with every load if the frequency of use is less than that described below.
  - a. **Daily**- ® Integrator strip (e.g. Steris Verify® or SPS Medical SteamPlus®) to assess steam sterilization, Weekly- biological indicators (BI) are used to assess the efficacy of steam sterilization (e.g., Steris Verify® Steam Test Pack with Self Contained Biological Indicators (SCBI) or SPS Medical SporView®) .
  - b. **Weekly**- BI's are used to assess efficacy of steam sterilization of liquids (e.g., Fisher Scientific MagnaAmp™).
  - c. **Daily**-an air removal test is used to monitor the effectiveness of mechanical air removal from pre-vacuum steam sterilizers (e.g., Steris Steraffirm™ Bowie-Dick Test or SPS Medical AirView™).
4. The Facility Manager is responsible for maintaining a log of autoclave equipment problems or failures, the corrective action taken, and how it is resolved.
5. It is the responsibility of the Facility Manager to retain autoclave records generated from the facility they manage for a **period of 6 months**.

### III. PROCEDURE

1. All Division autoclaves should be set for a temperature of 250 degrees Fahrenheit (122 degrees Celsius) for autoclaving microisolator caging. Higher temperatures can damage polycarbonate caging.
2. Steam chemical indicators (e.g., autoclave tape, steam indicator strips) should be used in each autoclave load. These indicators change color in the presence of steam and when placed on the surface of items are a quick visible indicator that the items have been autoclaved. Steam indicators should be used on the surface of packs, containers, biohazard bags, and items to indicate the contents have been autoclaved.
3. Multiparameter chemical indicators can be used to assess the parameters of steam sterilization by indicating if items have been exposed to steam for an adequate time, temperature, and steam quality (e.g., Steris Verify™ Sterilization Integrator Strips). Place strip in a location that is considered to be the hardest for steam to penetrate.
  - a. Surgical packs: place strip deep within the pack.
  - b. Microisolator cages: a strip within a cage.
  - c. Biohazardous caging: a strip within each cage.
  - d. Miscellaneous items/loads: place a strip in center of load
4. Daily, or with each load if autoclave is not used daily, test autoclave function by placing a Verify® 810110 Integrator or Steraffirm™ Steam Class 6 Emulating Chemical PCC013 sterilization indicator strip in the deep in the center of a load. Upon completion of the cycle compare the line of indicator ink with color standard.
5. The autoclave operator should view each strip once a load is removed from the autoclave. The indicator has been adequately exposed if the ink is as dark as or darker than the color standard. If the ink is lighter than the color standard, sufficient exposure to the sterilization process may not have occurred due to equipment malfunction or a procedural error in the sterilization process. If the indicator has not fully turned color, the operation of the autoclave should be reviewed, an entry is made on the **Equipment Log Sheet** in the **Autoclave Log Book**, and the load ran again. If the strip fails to indicate adequate exposure after the second attempt, notify the Facility Manager for corrective action.
6. Sterilization monitoring strips indicate whether appropriate time, temperature, steam quality are attained, but do not tell whether or not complete sterilization has occurred. To monitor whether the autoclave is completely sterilizing materials, steam test packs with biological indicators (e.g., Steris Verify® or SPS Medical SporView®) are used.
7. Steam test packs are single-use test packs designed for monitoring the effectiveness of common steam sterilizing processes, including 250°F (121°C) gravity cycles, and 270°F (132°C) pre-vacuum cycles. This test pack provides 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.

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 with 121<sup>0</sup>-124<sup>0</sup>C (250<sup>0</sup>-255<sup>0</sup>F) pre-vacuum sterilizers. The SPS Medical AirView™ Bowie-Dick or Steris DART® test packs are for use with 132<sup>0</sup> to 134<sup>0</sup>C (270<sup>0</sup>-274<sup>0</sup>F) 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<sup>0</sup>C/250<sup>0</sup>F 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<sup>0</sup> C/250<sup>0</sup> 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**.

#### **IV. SAFETY CONSIDERATIONS**

1. Care should be taken when removing indicators from autoclaves/cages, as they can be hot. Let the indicators cool before removing.
2. Heat resistant autoclave gloves should be worn whenever removing a load from an autoclave.
3. A properly operating autoclave is essential for safety. Perceived problems should be promptly reported to the Facility Manager for assessment and corrective action to be taken.

#### **V. DOCUMENTATION REQUIRED**

1. Autoclave Sterilization Record
  - a. Integrator strip - with each load
  - b. Air Removal Test – daily (when using pre-vacuum cycles)
  - c. Biological Indicators - weekly

#### **VI. REFERENCES**

1. SOP# 1007 Monitoring Autoclave Efficacy Using Biological Indicators
2. SOPs and Operating Manuals for each facility's autoclave.
3. Package insert directions of monitoring products.

**Approved:**

**Date:**