

SOP #: 512.01Title: **SOP -** Utilizing Steris Steraaffirm™ STEAM Emulating Indicators

Approvals:

Attending Veterinarian

Date:

8/20/13

1. Purpose

1.1 The intent of this standard operating procedure (SOP) is to describe how to properly use Steris Steraaffirm™ STEAM (Class 6) Emulating Indicators.

2. Responsibility

2.1 All ACF staff is responsible for following this SOP.

2.2 The Director of the Office of Laboratory Animal Research and facility supervisors must ensure compliance of this procedure and ensure staff is appropriately trained in the execution of this SOP.

3. Definitions

3.1 ACF - Animal Care Facility

3.2 Steris Steraaffirm™ STEAM (Class 6) Emulating Indicators: are cycle verification indicators that confirm the presence or absence of specific time and temperature parameters during a cycle, and integrate all the critical parameters of the steam sterilization cycle (temperature, saturated steam and exposure time). Emulating indicators can be placed inside each pack or pouch during sterilization of supplies or equipment in a validated pre-vacuum cycle. These emulating indicators can be used for routine monitoring of steam sterilization cycles.

4. Guidelines**4.1 Reagents/Materials****4.1.1 Steris Steraaffirm™ STEAM (Class 6) Emulating Indicators****4.1.1.1 Intended for use in steam sterilization.**

- 4.1.1.2 Designed for use in saturated steam sterilization cycles at 121°C/250°F for 15 minutes.

4.2 Equipment

- 4.2.1 Steris Finn-Aqua 122121-N-DP-B-LSR-AB Autoclave
- 4.2.2 Steris Autoclave located in AHC4 – V #531
- 4.2.3 Steris Autoclave (Serial# R810440202) located in OE – II #278

4.3 Safety Precautions

- 4.3.1 All personnel should be wearing required Personal Protection Equipment (PPE) as outlined in ACF SOP 511 throughout the Vivarium.
- 4.3.2 Autoclave surfaces can become extremely hot. Caution should be employed when retrieving and placing items, as well as, working in these areas.

4.4 Procedures

- 4.4.1 Place the Steraaffirm STEAM (Class 6) Emulating Indicators within the load in the “worst case” (least lethal location) in the load. This is usually at the bottom of the autoclave cart, close to the drain or the autoclave door.
- 4.4.2 Select the appropriate cycle and process the load.
- 4.4.3 Remove from the sterilizer and allow cooling before touching.
- 4.4.4 The chemical indicator on the label changes from yellow to a complete blue or purple color. Any other color (brown, green or any other color) indicates autoclave failure and appropriate supervisory personnel should be contacted and the load needs to be quarantined.
- 4.4.5 If the blue/purple color change is noticed, the autoclaved load is qualified and it can be used.

4.5 Storage

- 4.5.1 Store at temperature 32-86 °F, Relative Humidity of 30-60% and away from direct sunlight or near the steam autoclaves.
- 4.5.2 Do not use after expiration date printed on package. Expires on the first day of the expiration month noted on the box.

5. References