This sample policy and procedure is being provided to help you write your own policy and procedure for the use of this product in your facility. This sample should be edited as needed to comply with each facility's policy, procedures and compliance needs. It is the responsibility of each health care facility to develop policies and procedures that comply with its unique needs and allapplicable laws**,** rules, regulations, standards and industry recommended practices. For more information on the recommended use of this product, refer to the Instructions for Use provided with the product.

**Sterile Processing Department**

**Section:** Sterilization

**Title:**  Routine Sterilizer Efficacy Monitoring of Vaporized Hydrogen Peroxide
 Sterilizers

**Frequency:** Every Load

**Date:**

**POLICY: Evidence of effective vaporized hydrogen peroxide sterilization processes
 will be documented.**

*Rationale: Per ANSI/AAMI ST58, all gaseous chemical sterilization processes should be routinely tested. Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms known to be resistant to the mode of sterilization being monitored. Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization. For hydrogen peroxide sterilizers, AORN’s Guideline for Sterilization recommends using* Geobacillus stearothermophilus *biological indicators for routine sterilizer efficacy monitoring at least daily on each cycle type, preferably with each load. A quality assurance program that includes a negative biological indicator result in combination with physical monitors (i.e., sterilizer printouts) inspected to verify that cycle parameters were met and external and internal chemical indicators with acceptable end-point responses provides assurance that the sterilization process was effective.*

**Procedure**

1**.** A 3M™ Attest™ Rapid Readout Biological Indicator 1295 (1295 BI) is used to conduct routine sterilizer efficacy monitoring of every vaporized hydrogen peroxide sterilization cycle.

2. Place a 1295 BI and a 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (1248 CI) in a peel-open pouch indicated for use in hydrogen peroxide sterilization processes.

3. Place the pouched BI in the most challenging area of the sterilizer, with the white side of the pouch facing up. The sterilizer manufacturer’s IFU should be consulted to identify the area of the chamber least favorable to sterilization.

4. Run the sterilization cycle.

5. Within one hour of the completion of the cycle, retrieve, activate, and incubate the 1295 BI in a 3M™ Attest™ Auto-reader 490H according to instructions provided in the IFU.

6. Incubate a positive control 1295 BI having the same lot code as the test BI each day.

7. Document the lot codes and results of the test and control BIs.

8. Any positive result for a test BI must be reported to the Sterile Processing Manager immediately for further investigation and/or action.

**References**

1. ANSI/AAMI ST58:2013 *Chemical sterilization and high-level disinfection in health care facilities.*  Section 9.5.
2. AORN Guidelines for Perioperative Practice, 2017 Edition. *Guideline for Sterilization,* Recommendation XX.h
3. 3M™ Attest™ Rapid Readout Biological Indicator 1295 – manufacturer’s written IFU.
4. Brand X, Model Y Vaporized Hydrogen Peroxide Sterilizer - manufacturer’s written IFU.

3M, Attest, and Comply are trademarks of 3M Company.