UNIVERSITY OF TEXAS ARLINGTON | ENVIRONMENTAL HEALTH & SAFETY

STANDARD OPERATING PROCEDURE

STEAM CHEMICAL INTEGRATORS - STERILIZATION ASSURANCE - STEAM AUTOCLAVE KILL CYCLE

DYNAMICS OF STEAM STERILIZATION

Steam sterilization has been used for over 100 years. Decades of research have shown that the integrity of a steam sterilization process is the function of three basic parameters: time, temperature and the presence of saturated steam. All three are critical for effective steam sterilization. The importance of saturated steam is demonstrated when dry heat sterilization is compared with steam sterilization. The use of steam allows faster sterilization than dry heat. For example, dry heat sterilization requires a sterilization time of 60 minutes at 320°F (160°C), while steam sterilization at the same temperature would take less than a minute. Clearly, steam hastens the kill time of living organisms by many orders of magnitude and is generally preferable to dry heat. Because even small decreases in temperature during steam sterilization may significantly increase the time necessary for 100% kill, an accurate means of monitoring internal sterilizer conditions is essential.

AUTOCLAVE ACTION

Autoclave temperature, pressure, and time settings are very important to ensure adequate decontamination of biohazardous waste and thus render infectious material safe. Higher temperatures ensure more rapid killing. The most standard temperature/pressure combination employed is 250ºF (121ºC)/15 psi (pound-force per square inch**)**. Longer times are needed for larger loads, large volumes of liquid, and denser materials. When proper conditions and time are employed, no living organisms will survive the autoclave kill cycle. Exhaust settings should also be appropriate for the type of waste being autoclaved. FAST exhaust should be used for solid items and SLOW exhaust should be used for liquids.

Malfunctioning equipment can result in insufficient sterilization conditions inside of packaging as the result of:

- Incomplete air removal
- Inadequate cycle temperature
- Insufficient time at temperature
- Poor steam quality and quantity

Small reductions in time at temperature can reduce the margin of safety with steam processing. Problems that limit air removal or steam penetration in loads will have the effect of reducing the effective time at temperature.

IS YOUR AUTOCLAVE WORKING PROPERLY?

Biological waste is an important occupational hazard for people who work with the waste products of research and teaching laboratories. Biological (or special) waste has been identified by the Texas Board of Health as waste which requires special handling to protect human health or the environment. Biological waste is regulated by (1) the Texas Commission on Environmental Quality (TCEQ) and (2) the Texas Department of State Health Services (TDSHS). It is very important to be able to assure that viable biohazardous organisms are not sent to the landfill. If adequate steam does not contact with biohazardous materials, microorganisms can survive a trip through the autoclave. Autoclave tape is not a

reliable means to determine if the time, temperature, and pressure combination of the process was adequate to penetrate and kill microorganisms contained within the load.

Biological Indicators

Autoclaves used for kill loads are tested periodically by the Environmental Health and Safety Office (EH&S) for killing effectiveness through the use of **biological indicators** *(Geobacillus stearothermophilus* spore ampoules). Please, refer to SOP for Performance Verification of Steam Autoclave Kill Cycle.

Steam Chemical Integrators

3M™ Comply™ SteriGage™ Steam Chemical Integrators can be used inside each load to monitor time, temperature, and steam exposure conditions and can provide the necessary sterilization assurance needed when decontaminating biohazardous waste. Load control is the process by which a load is monitored and released based on the result of a **steam chemical indicator**.

3M™ Comply™ SteriGage™ Steam Chemical Integrators are chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked REJECT or ACCEPT (see Picture 1 on page 4). The extent of migration depends on steam, time, and temperature. Steam Chemical Integrators can be used for load control monitoring of all 118-138ºC (245-280ºF) steam sterilization cycles. Steam Chemical Integrators can't be used to monitor dry heat or other low temperature sterilization processes.

Instructions for Use of Steam Chemical Integrators

- Place a Comply SteriGage Steam Chemical Integrator inside each load to be autoclaved. Use autoclave tape to attach the steam chemical integrator to the inside of autoclave bag.
- Process the load according to established procedures (refer to SOP for Steam Autoclaves).
- After processing, remove the integrator from the autoclave bag and interpret the results.
- After processing, the dark color should have entered anywhere into the ACCEPT area window of the 3M™ Comply™ SteriGage™ Steam Chemical Integrator. This means that all the critical parameters of steam sterilization have been met.
- If the dark color is in the REJECT area window (has not entered the ACCEPT area window), this indicates a REJECT result which means that the items in the load were not exposed to sufficient steam sterilization conditions. The load should be returned for reprocessing and the cause of the sterilization process failure should be investigated.
- Record the steam chemical integrator test result in the autoclave waste treatment log (ACCEPT or REJECT).
- After use, the indicator will not visually change within 6 months when stored in conditions stated below in the "Storage and Shelf Life" section.

Safety of Steam Chemical Integrators

The design of the Comply SteriGage Steam Chemical Integrator prevents the indicating chemicals from coming in contact with handling personnel. The chemical, as a pellet before processing or a melted color front after processing, is contained in an envelope of impermeable top and bottom layers.

Storage and Shelf Life of Steam Chemical Integrators

Unopened and resealed packages need to be stored at 40-60% relative humidity conditions at room temperature [15-30ºC (59-86ºF)], away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.

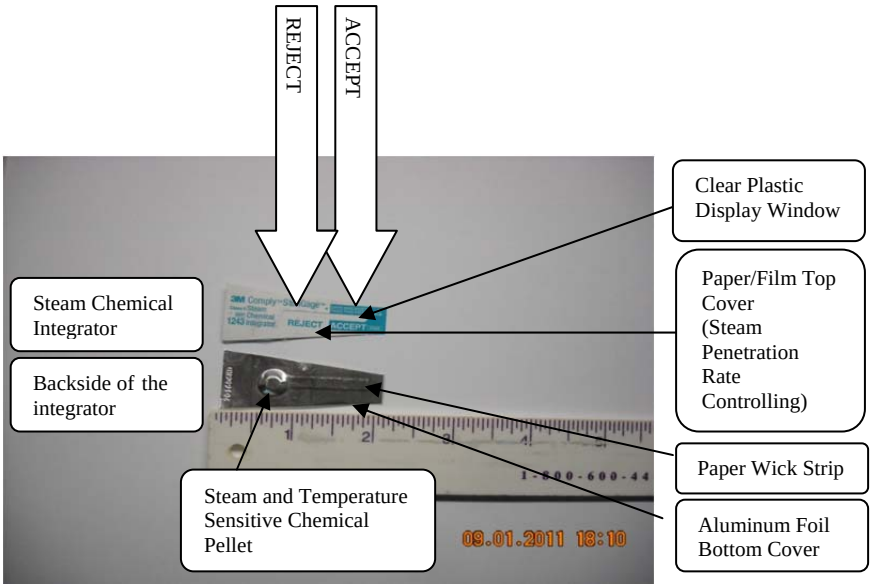
Comply Steam Chemical Integrators contained in an unopened package have a 5 year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

AUTOCLAVE MAINTENANCE

In addition to biological indicator / steam chemical integrator autoclave testing, autoclaves go through maintenance every four to six months as per service contracts to verify that they are functioning correctly. With the increasing concern for safe handling and disposal of infectious wastes, we must take the time and make the effort to ensure that our autoclaves are working properly. Please contact Merja Karwoski, Biological Safety Specialist, at 817-272-0068 with any questions or comments concerning autoclave testing and Raymond Jones, Engineering Research Associate, at 817-272-0090 with questions concerning maintenance of autoclaves in the Life Science Building and Engineering Research Building.

REFERENCES

1. The Texas Commission on Environmental Quality (TCEQ) rules: 30 Texas Administrative Code (TAC), Chapter 330.
2. The Texas Department of State Health Services (TDSHS) rules: 25 Texas Administrative Code (TAC), 1.131 – 37.



Picture 1. 3M™ Comply™ SteriGage™ Steam Chemical Integrator showing the window marked REJECT or ACCEPT and the functional components.