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 has 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 160°C (320°F), 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. Since even small decrease 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 to render infectious material safe. Higher temperatures ensure more rapid killing. The most standard temperature/pressure combination employed is 121°C (250°F) /15 pounds-force per square inch (lbf/in^2 or psi). 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 selected temperature
- Poor steam quality and quantity

Small reductions in time at selected sterilization 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 selected 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 defined in Title 30 Texas Administrative Code (30 TAC), Chapter 330, Section (§) 330.3(148) as waste which requires special handling to protect human health or the environment. Biological waste is regulated by the Texas Commission on Environmental Quality (TCEQ) and 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 have adequate 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 Environmental Health and Safety Office (EH&S) for killing effectiveness using **biological indicators** *(Geobacillus stearothermophilus* spore ampoules). Please, refer to SOP: Performance Verification of Steam Autoclave Kill Cycle.

Steam Chemical Indicators

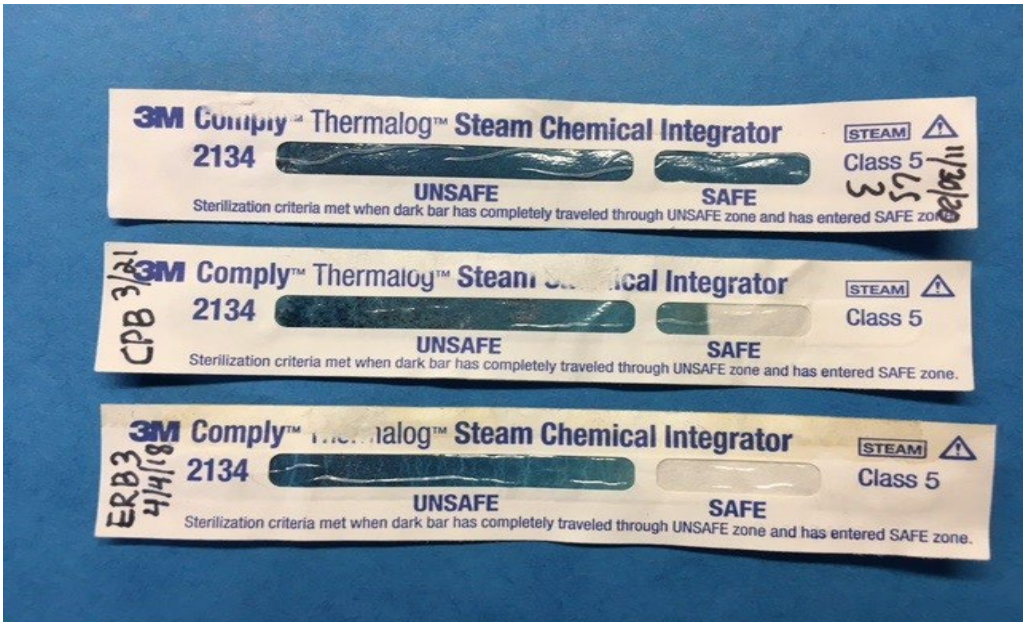
3M Comply™ Thermalog™ Steam Chemical Integrators can be used inside each load to be autoclaved to monitor time, temperature, and steam exposure conditions and can provide the necessary sterilization assurance needed when decontaminating biohazardous waste. Load control is the process by which a load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

3M Comply™ Thermalog™ Steam Chemical Integrators (later referred to as 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 UNSAFE or SAFE (Picture 1). The extent of migration depends on steam, time, and temperature. Steam Chemical Integrators can be used for load control monitoring of all 118-138°C (245-280°F) steam sterilization cycles. Steam Chemical Integrators can't be used to monitor dry heat or other low temperature sterilization processes.

Picture 1. 3M Comply™ Thermalog™ Steam Chemical Integrator (front and back) showing the window marked UNSAFE or SAFE.

Instructions for Use of Steam Chemical Integrators

- Place a Steam Chemical Integrator inside each load to be autoclaved. Use autoclave tape to attach the steam chemical integrator on inside of an autoclave bag.
- Process the load according to established procedures (refer to SOP: Steam Autoclaves).
- After processing, remove the Steam Chemical Integrator from the autoclave bag and interpret the results.
- The dark color should have entered anywhere into the SAFE area window of the Steam Chemical Integrator. This means that all the critical parameters of steam sterilization have been met.
- If the dark color is in the UNSAFE area window (has not entered the SAFE area window), this indicates a rejected 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. Please, see Picture 2.
- Record the Steam Chemical Integrator test result (SAFE or UNSAFE) in the Autoclave Waste Treatment Log (Form CO-EHS-F501) Autoclave Waste Treatment Log (CO-LS-F10).
- After use, the Steam Chemical Integrator will not change visually within 6 months when stored in conditions stated below in "Storage and Shelf Life" section.



Picture 2. 3M Comply™ Thermalog™ Steam Chemical Integrators from autoclaved loads. Two top Steam Chemical Integrators show that the process was successful, and loads are SAFE for disposal. The bottom Steam Chemical Integrator shows that process was not successful, and load is UNSAFE for disposal and needs to be reprocessed.

Safety of Steam Chemical Integrators

The design of the 3M Comply™ Thermalog™ Steam Chemical Integrator prevents the indicating chemicals from coming in contact with testing 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 package of 3M Comply™ Thermalog™ Steam Chemical Integrators needs to be stored at 40-60% relative humidity condition at room temperature [15-30°C (59-86°F)], away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.

3M Comply™ Thermalog™ 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 testing of autoclaves and the use of steam chemical integrators when autoclaving biohazardous waste, autoclaves go through maintenance according to service contracts to verify that they are functioning correctly. With the increasing concern for safe handling and disposal of infectious wastes, time must be taken, and every effort made to ensure that UT Arlington autoclaves are working properly. Please, contact the Biological Safety Specialist at 817-272-2185 with any questions or comments concerning autoclave testing, and the Life Sciences Core Facility Director at 817-271-9636 with questions concerning performance and maintenance of Life Science Building and Engineering Research Building autoclaves. Contact person for the Chemistry & Physics Building autoclave is Department of Chemistry & Biochemistry Research Engineer (817-272-3823) and for the Science & Engineering Innovation & Research Building (SEIR) autoclaves SEIR Building Facilities Manager (817-272-9046).

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