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DEPARTMENT OF BIOMEDICAL ENGINEERING

VII Semester

OBT357 BIOTECHNOLOGY IN HEALTH CARE

UNIT- 3 VACCINOLOGY

3.8 Instruments related to monitoring of Sterilization

- In vaccinology, ensuring sterility during vaccine production and administration is critical to prevent contamination and ensure safety.
- Monitoring sterilization processes involves specific instruments and indicators to verify that sterilization parameters are met.
- Below is an overview of the instruments and methods used for monitoring sterilization, particularly relevant to vaccinology, based on standard practices in healthcare and laboratory settings:

1. Physical Monitoring Instruments:

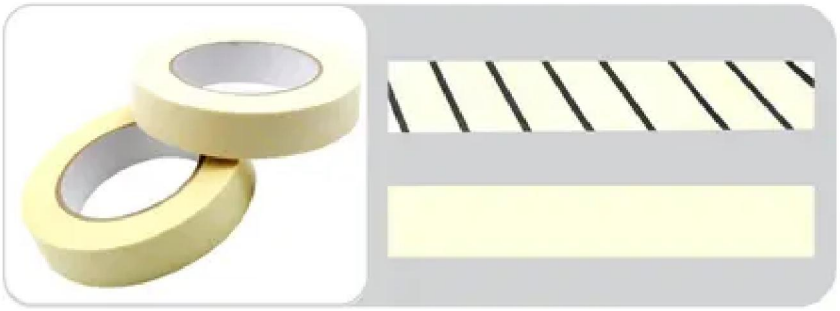
These instruments monitor the physical parameters of the sterilization process, such as temperature, pressure, and time.

- **Autoclave Gauges and Thermometers:** Autoclaves, which use steam under pressure to sterilize, are equipped with gauges and thermometers to display the real-time temperature and pressure. Staff check these instruments to confirm that the sterilization cycle has reached the required conditions (e.g., 121°C at 15 psi for 15-20 minutes).
- **Data Loggers:** Similar to those used for temperature monitoring of vaccines, data loggers can be placed inside an autoclave chamber to provide a continuous, detailed record of the temperature profile throughout the sterilization cycle.

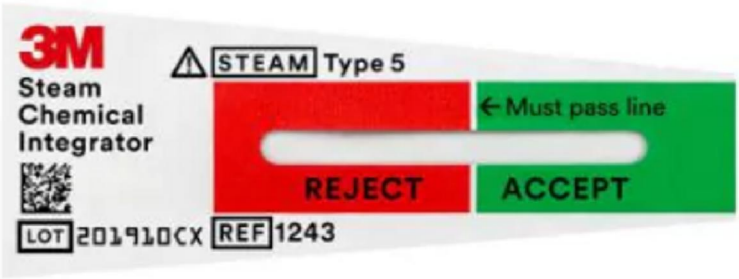
2. Chemical Indicators:

These are devices that change color or form when they are exposed to specific sterilization conditions. They provide a visual confirmation that the sterilization process has occurred. CIs are used to monitor sterilization of reusable tools and containers in vaccine manufacturing and to verify conditions in autoclaves or low-temperature sterilizers used for heat-sensitive materials

- **Sterilization Tape:** This adhesive tape is applied to the outside of packages. It has chemical stripes that change color when exposed to the correct temperature for a certain duration (e.g., a diagonal line that turns from white to black).



- **Integrators:** These are more advanced chemical indicators that respond to multiple parameters (temperature, time, and steam saturation). They are placed inside the sterilization package to verify that the sterilizing agent has penetrated to the center of the load. They often have a color change or a migrating front that indicates successful sterilization.



- **Autoclave Tape**: Chemically impregnated tape that changes color at high temperatures, used externally on packs to confirm exposure but not full sterilization. Tape indicators change color or display diagonal stripes, the words “sterile” or “autoclaved” when exposed to temperatures of 121°C. Tape indicators are typically placed on the exterior of the waste load.

3. Biological Indicators (Most Reliable):

Biological indicators (BIs) are considered the most reliable method for monitoring sterilization effectiveness. They directly test the process by using highly resistant bacterial spores.

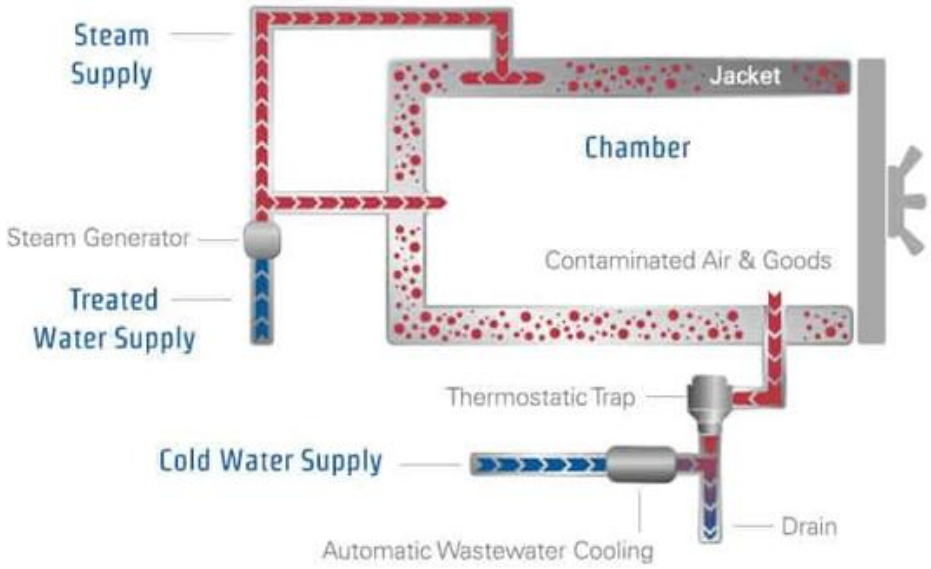
- **Spore Vials/Strips:** “A vial or paper strip with a known number of bacterial spores (like *Geobacillus stearothermophilus* for steam sterilization) is placed inside the sterilizer. After the process, the spores are incubated. If sterilization worked properly, no growth will appear, showing that even the toughest germs were killed. If growth is seen, it means the sterilization failed.”

- BIs are critical for validating sterilization of equipment used in vaccine production (e.g., bioreactors, filling needles) and ensuring sterile conditions during aseptic processing, where terminal sterilization isn’t always feasible (e.g., spray-dried vaccines).

4. Autoclaves and Sterilizers:

While primarily sterilization equipment, autoclaves and low-temperature sterilizers are equipped with monitoring systems to ensure proper function.

- **Steam Autoclaves**: Use steam under pressure (e.g., 121°C for 30 minutes or 132°C for 4 minutes) with built-in sensors for temperature and pressure. Monitoring includes integrators or BIs placed in the most challenging chamber locations.



- Steam is produced from the **treated water supply** in a steam generator.
- The steam is then supplied into the autoclave.
- Steam first enters the **jacket** (the outer layer around the chamber).
- This preheats the chamber walls and prevents condensation inside.
- Steam then enters the **chamber**, which contains the **contaminated goods and air**.
- The steam pushes out the air from the chamber (since steam is lighter than air).
- The **thermostatic trap** at the bottom allows the **air and cool steam** to escape.
- Only hot saturated steam remains inside, ensuring effective sterilization.
- The chamber is now full of **high-pressure, high-temperature steam**.

- The steam transfers heat efficiently, killing all microorganisms including resistant spores.
- After the sterilization time, steam is released.
- The hot wastewater is cooled with **cold water supply** before draining out (automatic wastewater cooling system).
- Once cooled, the sterilized goods are safe to remove.

- **Low-Temperature Sterilizers**: Systems using ethylene oxide (ETO), vaporized hydrogen peroxide (VHP), or peracetic acid have sensors to monitor gas concentration, humidity, and temperature.

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