Autoclave Safety and Surveillance Program

Sterilization is the process of treating an object or material to remove or kill all living organisms. Autoclaves are common laboratory equipment that requires high temperatures, steam and pressure to sterilize items such as glassware, media, instruments, and unwanted biological materials. The purpose for validating the autoclave performance is to be able to document that active human pathogens are not being disposed of in the trash.

Training

Because the conditions within autoclaves are so extreme, the chance for malfunction is high if not properly operated and maintained. Each autoclave has unique characteristics, so it is important for users to review and understand the operator's manual or receive training prior to use. Each lab is responsible for keeping training records.
Training should include:

- The location, function, and use of controls;
- Proper packaging, loading, unloading and testing procedures;
- Required Personal Protective Equipment;
- Maintenance and recordkeeping and:
- Emergency shut off procedures.

Safety Practices

Since any unsafe practice could result in injury to laboratory staff, the following safety precaution should be enforced when using autoclaves.

- Never attempt to autoclave items which contain hazardous chemicals or other hazardous materials (other than potentially infectious materials);
- Firmly lock autoclave doors prior to operation. Most autoclaves are equipped with an interlock system, which does not allow operation without the door being completely closed. Determine if your autoclave is equipped with an interlock system. If it does not, be sure all users are aware of this feature and advise them to utilize extra caution when operating the autoclave;
- Post signs to warn users or passers-by of the hazards present (e.g."Hot Surfaces, Keep Away"). Older autoclaves may not provide efficient heat shielding around the unit;
- Do not store combustible materials near autoclaves;
- Always utilize the appropriate PPE when handling items being placed into or removed from an autoclave. This includes heat resistant gloves, safety goggles, and if handling large amounts of liquid, rubber boots and rubber apron to protect against splash/spill hazards;
- Before loading the autoclave, check the inside for items left by previous users;
- Load autoclaves as per the manufacturer's recommendations. Not following these recommendations may result in incomplete sterilization of items;

- Loosen the caps of containers with liquids before loading to prevent bottles from shattering during pressurization;
- Use a tray with a solid bottom and walls to contain the contents and catch spills, should they occur. Add ¼ to ½ inch of water in the bottom of the tray to ensure bottles heat evenly;
- Check plastic materials to ensure they are compatible with the autoclave;
- Be sure autoclave is OFF and pressure is low before opening doors. Open autoclave doors slowly, keeping the head, face, and hands away from the opening to prevent direct contact with steam. Wait at least 30 seconds after opening the door before reaching into the autoclave to remove sterilized items. Wearing appropriate gloves and protective equipment, remove items slowly;
- Allow glassware to cool for at least 15 minutes prior to touching with ungloved hands for non-liquid loads;
- Allow liquids to stand for at least 1 hour prior to touching with ungloved hands; and
- Ensure all manufacturer safety recommendations are in place and effectively enforced. If injury occurs from exposure to autoclave steam or autoclaved materials, follow procedures for treatment of a burn and seek immediate medical attention.

Basic Cycles Description and Typical Application or Load Type

- **Gravity** cycle is the most basic sterilization cycle. Steam displaces air in the chamber by gravity (i.e. without mechanical assistance) through a drain port. Gravity cycles are used to sterilize glassware, unwrapped goods, waste, utensils, and unwanted biological materials.

- **Pre-Vacuum** cycle mechanically removes air from the chamber and load through a series of vacuum and pressure pulses. This allows the steam to penetrate porous areas of the load that couldn't otherwise be reached with simple gravity displacement. Pre-Vacuum cycles are used to sterilize wrapped goods, packs, animal cage bedding, cages, porous materials, and unwanted biological materials.

- **Liquid** cycle is used to sterilize liquids by slowly exhausting the chamber in order to prevent boil over of the liquid. Liquids should only be sterilized using the Liquid cycle. Never attempt to autoclave flammable liquids or other hazardous chemicals. Ensure that the container you use has room for liquid expansion and do not autoclave closed containers. Be sure that if caps are used, they are only loosely applied. Place bottles of liquid to be autoclaved in a tray with a couple of inches of water in the bottom. Do not allow hot bottles of liquids to be jolted, this can cause hot bottle explosions. The greater the volume to be sterilized, the greater the exposure time is needed. The chart below depicts the required sterilization time per volume of liquid.

Temperature Setting	Liquid Quantity (ml)	Time Setting (minutes)
250°F (121°C)	75	25
250°F (121°C)	250	30
250°F (121°C)	500	40
250°F (121°C)	1000	45
250°F (121°C)	1500	50
250°F (121°C)	2000	55

Monitoring Autoclave Effectiveness and Record Keeping

Sterilization procedures should be monitored through a combination of mechanical, chemical, and biological techniques designed to evaluate the sterilizing conditions and the procedure's effectiveness.

Mechanical techniques for monitoring sterilization include assessing the cycle time, temperature, and pressure. For sterilizers that have recording devices that print out these parameters, these tapes should be kept with the usage records. Correct readings do not ensure sterilization, but incorrect readings could be the first indication that a problem has occurred with the sterilization cycle. Usage records of each run should be kept in the autoclave room. The record should include the date and time of the run, the name of the person performing the run, the name of the Principle Investigator, the chosen cycle, and the size of the load (full or partial). The UM System Business Policy Manual Record Retention Policy states that equipment maintenance records should be kept for one year after the disposition of the equipment. The department may develop a record retention policy for review by Records Management.

Chemical indicators, use sensitive chemicals to assess physical conditions such as temperature during the sterilization process. Chemical indicators such as heat sensitive tape change color rapidly when a given parameter is reached. Indicator test results are shown immediately after the sterilization cycle is complete and could provide an early indication of a problem and where the problem occurred in the process. If the external indicator suggests inadequate processing, the item that has been processed may not be sterile. Because chemical indicators do not prove sterilization has been achieved, a biological indicator (i.e., spore test) is required.

Biological indicators (BIs) are the most accepted means of monitoring the sterilization process because they directly determine whether the most resistant microorganisms (e.g., Geobacillus or Bacillus species) are present rather than merely determine whether the physical and chemical conditions necessary for sterilization are met. Because spores used in BIs are resistant and in high numbers, an inactivated BI indicates that other potential pathogens in the load have also been killed. Test packs or bags used to test BIs, should be run as closely to the actual conditions as can reasonably be simulated. Most BIs require incubation of the autoclaved test vial with a non-autoclaved control vial, over a 48 hour period. If a BI test fails (growth occurred in the autoclaved vial), the autoclave should be taken out of service. Run parameters should be verified as being within previously acceptable limits. The validation procedure should be reviewed to determine if operator error could have caused the failure. If there are no identifiable causes for the failure, the autoclave should be serviced. After service, the BI validation should be repeated.

Autoclave Validation Schedules

- Autoclaves should be validated with a biological indicator as part of installation of an autoclave, to validate a new cycle protocol and after repairs.

- For autoclaves not used to inactivate biohazardous waste, validation should be performed at least once every six months.

- For autoclaves used for the inactivation of biological materials classified as BSL-2 or ABLS-2, the autoclave should be validated every 40 hours of use, or monthly, whichever is shorter. For teaching labs that produce waste containing BSL-2 organisms, the autoclave should be validated before the first load is run and then every 40 hours of use, or monthly until the class is concluded. The autoclave can then go back to a semi-annual validation schedule.