DRAFT

"The attached draft information is provided as a tool for organizations developing their own means for evaluating medical waste treatment technologies. This information is provided only as a framework and is not for distribution and should not in any way be interpreted or represented as an official EPA document or test protocol."

STEAM AUTOCLAVE

DESCRIPTION: Steam autoclave treatment combines moisture, heat, and pressure to inactivate microorganisms. All steam autoclaves are constructed with a metal chamber to withstand the increased pressure/temperature. Autoclaves come in two basic varieties, gravity displacement and prevacuum autoclaves. The size of the devices may vary from benchtop models to large commercial models which can treat more than a ton of waste per cycle.

OPERATING PARAMETERS: The factors that affect the efficacy of steam autoclave treatment of medical waste are those affecting the internal waste load temperature, steam penetration of the waste, and the duration of treatment. These factors include:

- temperature and pressure achieved by the autoclave
- size of the waste load
- composition of the waste load
- steam penetration of the waste
- packaging of the waste for treatment
- orientation of the waste load within the autoclave

Steam autoclaves operate most effectively when the temperature measured at the center of the waste load approaches 121 °C and there is adequate steam penetration of the waste load under pressure.

WASTES SUITABLE FOR TREATMENT BY STEAM AUTOCLAVING: All wastes with the exceptions of body parts and contaminated animal carcasses which are excluded from treatment by steam autoclaving because the density of the waste items prevents adequate steam penetration. Radioactive, hazardous, and cytotoxic wastes are also inappropriate for treatment by steam autoclaving.

INDICATOR ORGANISMS: Thermally resistant indicator organisms are selected to provide a maximum challenge. *Bacillus subtilis* (globigii) ATCC 9372 (10^4) may be used to demonstrate a 4 $\log_{10}$ reduction of viable spores.

Bacillus stearothermophilus ATCC 12980 (10^6) may be used to demonstrate a 6 $\log_{10}$ reduction of viable spores.

TEST PROCEDURE: Dried test spores are placed in a thermally resistant and steam permeable container near the center of the waste load. The autoclave is operated under normal conditions. At the conclusion of the cycle the test organisms are removed from the load and recovered within 24 hours. To recover the test organism the test discs or strips should be aseptically inoculated into 5.0 mL soybean-casein digest broth medium (or equivalent) and incubated for at least 48 hours (30 °C for *B. subtilis* or 55 °C for *B. stearothermophilus*). At the end of the incubation period the media should be examined for turbidity as a sign of bacterial growth. Any growth should be subcultured onto appropriate media to confirm the identity of the organism as the indicator organism or an environmental contaminant.