SAMPLE WASTE TREATMENT VACUUM AUTOCLAVE TECHNICAL SPECIFICATIONS

INTRODUCTION

The UNDP GEF Project is procuring non-incineration treatment technologies for demonstration in model facilities or model central treatment facilities. This guidance gives an example of technical specifications for vacuum autoclaves used in treating healthcare waste. It should be modified for the specific requirements of the model facility and country. Note that these specifications are geared towards vacuum autoclaves and would have to be modified to cover other types of treatment technologies such as microwave systems.

VACUUM AUTOCLAVES

Autoclaves have been used for over a century to sterilize medical instruments. In the last several decades, they have been adapted for the treatment of infectious waste. An autoclave consists of a metal vessel designed to withstand high pressures, with a sealable door and an arrangement of pipes and valves through which steam is introduced into and removed from the vessel. Some autoclaves are designed with a steam jacket surrounding the vessel; steam is introduced into both the outside jacket and the inside chamber. Heating the outside jacket reduces condensation on the inside chamber wall and allows the use of steam at lower temperatures. An autoclave without a steam jacket, sometimes called a retort, is commonly used in large-scale applications and is cheaper to construct.

Because air is an effective insulator and a paramount factor in determining the efficiency of steam treatment, removal of air from the autoclave is essential to ensure penetration of heat into the waste. Autoclaves can be subcategorized according to the method of air removal. The three common types are:

- gravity displacement autoclaves
- pre-vacuum or high vacuum autoclaves
- pressure pulse autoclaves.

In a gravity-displacement autoclave, steam is introduced under pressure into the chamber forcing the heavier air downward into an outlet port of the chamber. A more effective but somewhat costlier method is the use of a vacuum pump and/or a steam ejector, as in vacuum autoclaves (also called high vacuum autoclaves). Pre-vacuum autoclaves pull a vacuum before introducing steam and need less time for disinfection due to their greater efficiency in removing air and disinfecting waste. Many vacuum autoclaves also use a vacuum to remove and condense the steam after treatment. Other autoclaves use pressure pulsing to evacuate air. The

three basic types of pressure pulsing systems are: pressure gravity, vacuum pulsing, and pressure-vacuum. Pressure gravity or steam flushing entails repeatedly releasing steam and reducing the pressure to near atmospheric pressure after the pressure has reached a pre-determined level and then allowing the pressure to build up again with the addition of steam. Vacuum pulsing is similar to a high vacuum operation except that two or more vacuum cycles are used at the start of the treatment process. Pressure-vacuum systems operate by building pressure then pulling a vacuum and repeating this process several times during treatment. Alternating pressure cycles are used to achieve rapid penetration of steam. In general, the pressure-vacuum systems have the shortest time for achieving high disinfection levels. It is essential, however, that air removed from the autoclave is treated or filtered to prevent the spread of aerosolized pathogens.

Since autoclaves must be able to withstand repeated buildup and release of steam pressures, autoclaves must meet basic requirements on construction materials, engineering design, fabrication, accuracy of pressure and temperature sensors, testing, etc. in order to operate safely. Examples of international standards related to pressure vessels are EN 13445, EN 285 and ASME Boiler and Pressure Vessel Code section VIII. For waste treatment, autoclaves should be rated to operate between 1 to 2 bar gauge pressure (about 15 psig to 30 psig, or 1540 to 2280 mm Hg absolute) or higher.

Vacuum autoclaves are manufactured in a wide range of sizes. Some are designed to treat several kilograms per hour to large capacity autoclave capable of treating several tonnes per hour. The large autoclave vessels have inner diameters of 1 to 2 meters or larger, with lengths ranging from 2 to more than 7 meters.

A typical operation for a vacuum autoclave involves the following:

- Waste collection: Infectious waste bags are placed in a perforated metal cart or bin. As an option, the cart or bin is lined with autoclavable plastic liners that allow steam to penetrate but prevent waste from sticking to the container.
- Pre-heating (for autoclaves with steam jackets): Steam is introduced into the outside jacket of the autoclave.
- Waste loading: The metal cart or bin is loaded into the autoclave chamber. With every load, a color-changing indicator is attached to the outer surface of the waste bag in the middle of the waste load to monitor treatment. The charging door is closed, sealing the chamber.
- Air evacuation: Air is removed through pre-vacuuming or pulse vacuuming as explained above. The exhaust air is filtered or treated before being released to the atmosphere.
- Steam treatment: Steam is introduced into the chamber until the required pressure or temperature is reached. Additional steam is automatically fed into the chamber to maintain the temperature and pressure for a set time period. Pressure pulsing autoclaves vary the pressure according to a set process cycle.

- Steam discharge: Steam is vented from the chamber, usually through a condenser, to reduce the pressure and temperature. In many systems, a post-vacuum cycle is used to remove residual steam and dry the waste.
- Unloading: Usually, additional time is provided to allow the waste to cool down further, after which the treated waste is removed and the indicator strip is evaluated. The process is repeated if the color-changing indicator shows that the treatment cycle was insufficient.
- Documentation: A log is maintained to record the date, time, and operator name; amount of waste treated; automatic equipment recording of time-temperature-pressure; and results of monitoring indicators, such as a steam integrator strip.
- Mechanical treatment: If desired, the treated waste is fed into a shredder or compactor prior to disposal in a landfill.

Some options provided by autoclave manufacturers include programmable computer controls, tracks and lifts for carts, recording of treatment parameters, weighing scales, autoclavable carts and cart washers, odor reducing systems, sensors to detect radioactive or chemical wastes, and shredders. Certain load configurations, such as placing bags in multi-level racks with sufficient spaces between bags to allow more surfaces to be exposed to steam, are more efficient than tightly stacked containers or carts piled with waste bags. Autoclave facilities should have sufficient ventilation to minimize odors in the work space.

Autoclaves are capable of treating the range of infectious waste including cultures and stocks, sharps, materials contaminated with blood and limited amounts of fluids, isolation and surgery waste, laboratory waste (excluding chemical waste), and soft waste (gauze, bandages, drapes, gowns, bedding, etc.) from patient care. Waste solvents, chemotherapeutic waste, mercury, other hazardous chemical wastes, and radioactive waste should not be treated in an autoclave.

Treated waste from an autoclave retains its physical appearance. If desired, a mechanical process such as a shredder or grinder is used after treatment to make the waste unrecognizable. Shredding can reduce the volume of the treated waste by as much as 85 percent. Compaction could reduce waste volume by about 60 percent.

The operation of autoclaves requires the proper combination of temperature/pressure and exposure time to achieve disinfection. In the past, a minimum recommended temperature-exposure time criterion of 121°C for 30 minutes was suggested. This corresponds to a pressure of 205 kPa or 2.05 bar (15 psig or 30 psia). However, the effective penetration of steam and moist heat depends on many factors including time, temperature/pressure, process sequence, load size, stacking configuration and packing density, types and integrity of bags or containers used, physical properties of the materials in the waste (such as bulk density, heat capacity and thermal conductivity), the amount of residual air, and the moisture content in the waste.

For this reason, initial challenge tests should be conducted using waste samples that are representative of real waste and placed in the manner in which the waste will be treated in order to determine or validate the minimum temperature, pressure and exposure time or pulsing cycle required to achieve the microbial inactivation standard. (See UNDP GEF Guidance document "Guidance on Microbiological Challenge Testing for Medical Waste Autoclaves".)

SAMPLE TECHNICAL SPECIFICATIONS

These technical specifications should be modified to fit the specific requirements of the model facility.

Equipment:	High vacuum healthcare waste treatment autoclave
Capacity:	For batch units: minimum of xxxx liters per cycle or xxxx kg per cycle [specify the cycle time] For continuous or semi-continuous units: xxxx kg/hour
Minimum working pressure:	2 bars (30 psig) or higher
Minimum working temperature:	121°C (250°F) or higher
Footprint:	Entire system must fit within an enclosed space of yyyy cm x yyyy cm x yyyy cm height
Pressure vessel standard	Must comply with ASME Boiler and Pressure Vessel Code Section VIII or EN 13445
Safety feature – redundant overpressure features	Overpressure sensor linked to a pressure relief safety valve plus a rupture disc or equivalent pressure limiting device to keep the pressure below the maximum allowable pressure
Safety feature – door interlock	Door interlock system to prevent opening door while vessel is under pressure; safety feature shall also prevent start-up if the door is not properly closed
Safety feature – emergency shut-off	Emergency shut-off button in a readily accessible location
Safety feature – "person in vessel" safety device [for large autoclaves only]	Internal switch cable or equivalent device interlocked with the alarm or control system to prevent start-up if a person is inside the vessel
Safety feature – protection from hot surfaces	External insulation to prevent hot surfaces that may come in contact with workers exceeding 50°C
Safety feature – accidental vacuum breaker	Accidental vacuum breaker valve to prevent an accidental high vacuum during a power outage
Materials of construction:	Materials in contact with steam shall resist attack from steam and condensate, not cause deterioration of the quality of the steam, and not release any substances known to be toxic in such quantities that could create a health or environmental hazard. (See Annex C of EN 285:2006+A2:2009 for examples of recommended materials.)
Microbiological inactivation efficacy:	Meets STAATT Level III microbial inactivation efficacy criteria at specified operating parameters as shown by challenge test results from an independent third party (Criteria: 6 log reduction or higher of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria as demonstrated using *Mycobacterium phlei* or *Mycobacterium bovis* (BCG); 4 log reduction or higher of heat-resistant spores as demonstrated using *Geobacillus stearothermophilus* or *Bacillus atrophaeus*)

Door:	Quick opening door (e.g., rotating locking ring (breech lock) or equivalent)
Electrical:	Xxxx VAC, xxxx-phase, xxxx-Hz
Electrical safety:	Meets the requirements of IEC 61010-2-040, UL 61010A-2-041, or equivalent electrical safety standard; Meets electromagnetic compatibility requirements under EN 61326:1997 or equivalent
Controls:	The autoclave shall be operated by controls to permit automatic operation using one or more pre-set operating cycles. Measurements of chamber temperature and pressure shall be fitted with a broken sensor monitoring system. For purposes of maintenance, testing, or in cases of emergency, means shall be provided to permit the sequential manual operation of the process. The sterilizer shall be protected against the effects of short circuit in inputs and outputs that are connected to the controller.
Display indicators:	Pressure and temperature readable by normal vision from a distance of (1.00 ± 0.15) m
Other indicator displays:	Displays indicating: door locked, operation in progress, major operating cycles, and cycle complete; as well as fault condition
Indicator for temperature	± 1% accuracy or better over the scale range 50°C to 150°C; 0.1°C resolution for digital instruments
Indicator for pressure	± 1.6% or better over the scale range -1 bar to 3 bar; 0.01 bar resolution for digital instruments
Indicators for processing time	Error not to exceed 1%
Fault condition:	In the event of a failure of the automatic controls, a means to return to atmospheric pressure shall be provided. If values of the process variables exceed the limits specified by the manufacturer, or if a failure occurs that prevents the completion of the process, the controls shall show a visual indication of failure and an audible alarm which can be mutable. A broken sensor shall cause a fault to be indicated.
Recording:	Recording of time, temperature and pressure can be digital or analog and shall include values during transition points throughout the operating cycle sufficient to confirm that cycle parameters have been achieved and maintained within the manufacturer's specified tolerances. Printed records should be readable for not less than 5 years. Pressure readings shall have an accuracy of ±1.6% over the range of -1 to 3 bars. Temperature readings shall have an accuracy of ±1% or better over the range 50°C to 150°C. Time periods of 5 minutes or more shall have an accuracy of ±1% or better.
Vacuum:	Minimum -xxxx mmHg vacuum; meets section 8.2.2 of EN 285:2006+A2:2009 (i.e., uniform color change throughout a Bowie-Dick indicator when tested on the empty autoclave)
Decontamination of air:	Air removed during the vacuum cycle must be decontaminated by means of a HEPA filter (Class H14 or higher, EN 1822; or >99.97% efficiency on 0.3 micron particles, IEST-RP-CC001), HEPA with activated carbon filtration, steam treatment, or other equivalent method to prevent release of pathogenic aerosols
Loading and unloading system:	Ramp, lift, internal tracks, pull-out trays, or other means to facilitate loading of waste bins into the autoclave
Markings:	Markings for safety shall comply with EN 13445 or ASME BPV Code Section VIII, EN 61010-1, and EN 61010-2-040 or UL

	61010A-2-041 or equivalent
Auxiliary equipment:	
Steam generator	Steam generator or boiler properly sized for the autoclave – specify if electric boiler or gas or oil boiler is desired. For electrical boilers, specify electrical requirements; for gas or oil, specify which type of fuel is required. If the healthcare facility already has steam available, do not include a steam generator or boiler but specify the steam temperature/pressure available.
Autoclavable bins	Autoclavable bins of aluminum or stainless steel (the number of bins should be at least twice the number of bins that fit inside the autoclave)
Other requirements:	
	Operating and service manual in xxxx language
	One (1) year warranty on parts and service after commissioning and acceptance
	On-site training provided to operators
Optional equipment:	
	Odor control system to supplement the roof exhaust ventilation
	Removable and easy-to-clean screen plug to prevent clogging of the condensate discharge line
	Water treatment or softening system: If a steam generator or boiler is specified and if water for the boiler is hard water or untreated water, include a water treatment system for the boiler water [Note: specifications for the water treatment or water softening system depend on test results of the water to be used for boiler water make-up]
	Automatic loader or tipper
	Compactor for treated waste
	High torque shredder specifically designed for shredding treated healthcare waste

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