Technical Specifications for Hybrid Autoclaves

#	Criterion	Basis for Selection
1	Equipment	Hybrid or advanced autoclave specifically designed for medical waste, including a rotating autoclave; hydroclave; autoclave with internal shredder, macerator, fragmenting arms or mixing arms; autoclave with integrated pre-treatment shredder; or steam treatment system using circulation through an internal shredder or macerator
2	Capacity	
3	Footprint	The autoclave system shall fit in a space of ____m x ____m x ____m height. Equipment and accessories shall be able to pass through a door opening of ____m width x ____m height.
4	If the technology includes a pressure vessel subjected to an internal gauge pressure greater than 0.5 bar:	The pressure vessel shall comply with ASME Boiler and Pressure Vessel Code Section VIII, and/or European standard EN 13445, including hydrostatic testing requirements.
5		The pressure vessel shall have redundant overpressure protection and an emergency shut-off button or switch in a readily accessible location.
6	Material of construction of the sterilization chamber	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.
7	Microbiological inactivation efficacy	The hybrid autoclave system shall meet STAATT Level III microbial inactivation efficacy criteria at the operating parameters as shown by challenge test results (Criteria: 4 log reduction or higher of heat-resistant spores as demonstrated using *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores).
8	Electrical	_____ V, ____-phase, ____ Hz electrical power is available at the site.
9	Electrical safety	The hybrid autoclave system shall meet the requirements of IEC 61010-2-040, UL 61010A-2-041, or an equivalent electrical safety standard; as well as the electromagnetic compatibility requirements under EN 61326:1997 or equivalent standard.
10	If the technology includes pre-treatment or internal shredding, maceration, fragmentation or mixing:	The system shall be designed to prevent the release to the workplace air of untreated gases, liquids or aerosols at any time during pre-treatment or internal shredding, maceration, fragmentation or mixing. Any gases, liquids or aerosols released during pre-treatment or internal shredding, maceration, fragmentation or mixing shall be decontaminated by means of steam treatment, a HEPA filter (Class H13 or higher, EN 1822; or >99.97% efficiency on 0.3 micron particles, IEST-RP-CC001), HEPA with activated carbon filtration, or other decontamination method effective in preventing the release of pathogens into the workplace air.
11		The shredder, macerator, fragmentor or mixer shall be designed to prevent the ejection of projectiles outside its housing at any time during pre-treatment or internal shredding, maceration, fragmentation or mixing, and in the event of a failure of the shredder, macerator, fragmenting arms or mixing arms.
12		The shredder, macerator, fragmentor or mixer shall be of a robust

		design requiring minimum maintenance and shall be able to handle sharps, needles, syringes, blades, glass vials, broken ampoules, plastics, intravenous sets/bottles, blood bags, gloves, bandages and other soft waste.
13		The shredder, macerator, fragmentor or mixer shall be designed to minimize noise (no higher than 85 dBA) and vibration.
14		If the chamber with a shredder, macerator or high-speed mixer has a hopper lid or door for loading of medical waste, the shredder, macerator or high-speed mixer shall stop automatically if the hopper lid or door is opened to load waste.
15		The shredder, macerator, fragmentor or mixer shall be designed to deal safely with shock-loading, overloading or jamming.
16		The shredder, macerator, fragmentor or mixer shall be designed to maximize operator safety from mechanical and electrical hazards.
17	Controls	The hybrid autoclave shall be operated by controls to permit automatic operation. The control system shall include an emergency shut-down switch or button. The autoclave shall be protected against the effects of electrical short circuits.
18	Display indicators	Pressure and temperature readable by normal vision from a distance of 1.00m.
19	Other indicator displays	Displays indicating: operation in progress and cycle complete; as well as fault condition.
20	Indicator for temperature	± 1% accuracy over the scale range 50°C to 150°C; 0.1°C resolution for digital instruments.
21	Indicator for pressure	± 1.6% over the scale range -1 bar to 3 bar; 0.01 bar resolution for digital instruments.
22	Indicators for time	Error not to exceed 1% of the indicated time in hours or minutes as applicable.
23	Fault condition	In the event of a failure that prevents the completion of the process, the controls shall show a visual indication of failure and an audible alarm.
24	Recording	Recording of operating parameters can be digital or analog and shall include values 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 2 years.
25	Typical service life	10 years
26	Waste loading system	The system shall have a means for loading the waste in a manner that protects the operator from occupational hazard, including exposure to infectious agents, back injuries and repetitive strain injuries.
27	Accessories (e.g., bins, carts, conveyors, cart washing equipment, etc.	Specify: _____
28	Spare parts for one year of operation	
29	Operating and service manual in _____ language.	
30	One (1) year warranty on parts and service after commissioning and acceptance.	
31	On-site training provided to operators as outlined in the Schedule of Requirements.	