Procedure for the Validation of a Medical Waste Autoclave

Background

The purpose of validation testing is to determine the operating parameters required to achieve the efficacy standard [minimum required log reduction of spores] of the state wherein the system is operated. The testing is done at the system's maximum loading capacity; with test packages simulating the facility's specific waste stream; and using the services actually provided at that facility [steam pressure, steam quality, air pressure etc.].

The operating parameters, loading capacity, and residence time recommended by the equipment manufacturer for the facility's waste stream will be used as the initial testing point for the system.

The use of sealed spore suspension ampoules is specified.

Test packages and samples should always simulate a "representative challenge" that is anticipated for the facility.

Based on the results of the initial testing, additional tests may be required to provide sufficient data to determine the actual operating parameters specific to the facility. These additional tests may include variations in operating parameters as necessary to achieve the required efficacy.

Upon completion of the testing, a detailed report will be provided. This report will include temperature, pressure and biological indicator results. The report will also state the proper operating parameters, maximum loading capacity and waste stream components certified for the system as determined by the testing.

Test packages will be prepared as follows:

Select the test packages that are appropriate for the facility's specific waste stream from those listed below. For example, a facility that uses an outside sharps service may not require the testing of large (laboratory) sharps containers [Test Package Type B]. The remainder of the weight, in excess of the test package weight, required to achieve the manufacture's recommended maximum weight should consist of medical waste from the facility. Commercial facilities should place the test packages inside the boxes or containers consistent with the packaging in which it is processed.

Test Package Type A - "Red Bag" - e.g. Patient Rooms

1. Prepare Biological Indicators
    a. Tape 2 ampoules onto a 3x5 card
    b. Program and affix temperature recorder (if used) to the card.
    c. With permanent marker note the sample number, recorder number and position on each card.

2. Fill an autoclavable bag (31x43-1.2mil) with a mixture of surrogate RMW to a weight typical of those found at the facility.
   Typical Contents;
   - Textiles (sheets, gauze, isolation gowns)
   - Plastics (bottles, tubing, trays)
   - Liquid, 12 ounces of water
3. Bury the prepared Biological Indicator card in the bag of mixed material.
4. Loosely tie the bag closed.
5. Mark the outside of the bag with "TYPE A" & "PKG #"

Test Package Type B - "Large Sharps Container" - e.g. Laboratory

1. Prepare Biological Indicators
   a. Tape 2 ampoules onto a 3x5 card
   b. Program and affix temperature recorder (if used) to the card.
   c. With permanent marker note the sample number, recorder number and position on each card.
2. Package Assembly
   a. Place 3 inches of clean, unused, "sharps" material into a 17 gallon sharps container.
      Typical Contents;
      - Needless syringes
      - Vacutainer Tubes
   b. Place the prepared Biological Indicator card in the container
   c. Fill the balance of the container with the same mixture of surrogate material.
   d. Add 32 ounces of liquid to the container
3. Secure and close the lid onto the container
4. Mark the outside of the bag with "TYPE B" & "PKG #"

Test Package Type C - "Suction Canister" - e.g. OR/ER/CIC

1. Prepare 2 Biological Indicators
   a. Mark ampoules for identification
      i. Wire markers work well on the neck of the ampoule
2. Obtain unused suction canisters typically in use at the facility.
3. Suction Canister Assembly (prepare canisters, one with solidifier, one with water only)
   a. Fill the first suction canister with water and solidifier following the solidifier manufacturer's directions.
   b. Using a thin dowel or rigid tube, press an ampoule into the center of the solidified water and work solidified material to fill the hole above the ampoule.
   c. Program and similarly press a temperature recorder into the solidified material.
   d. Attach the lid to the canister and plug or cap all of the holes according to the manufacturer's directions.

e. Fill the second canister with water only, insert ampoule and temperature recorder, then seal.

6. Fill an autoclavable bag (31x43-1.2mil) with a mixture of surrogate RMW to a weight typical of those found at the facility.
   Typical Contents;
   - Textiles (sheets, gauze, isolation gowns)
   - Plastics (bottles, tubing, trays)
   - Liquid, 12 ounces of water
4. Bury the two prepared suction canisters in the bag of mixed material.
5. Loosely tie the bag closed.
6. Mark the outside of the bag with “TYPE C” & “PKG #”

The test load will be prepared as follows:

1. If bin liners are used, fit the liner into the bin.
2. Place the prepared Test Packages A, B and C, into the bins marking each bin to identify it, recording the weight of each bin and the total load weight.
3. The bag packages (A and C) are placed on the bottom of the bin and the large sharps package (B) is placed standing in the upright position.
4. Fill the balance of each bin with bagged waste material of RMW. {If the equipment is a ‘Chamber Only’ design [i.e. does not use bins] the test packages should be placed in the center of the load, surrounded on all sides by waste}

Test Package placement within the load

- *Systems with two or three bins should have at least one test package placed in each bin.*
- *Systems with more than three bins should have the test packages placed in the bins at the front, center and rear of the vessel.*
- *Test packages B and C should always be placed in the bins that are farthest away from the main steam inlet.*

5. Place one temperature recorder and one pressure recorder each near the appropriate fixed sensors inside the vessel.
6. Close door and initiate the cycle as per manufacture’s recommended procedure. (If machine is equipped with multiple cycle capability, separate tests must be completed or each cycle type)

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Upon completion of the initial testing cycle:

1. Retrieve the ampoules and temperature/pressure recorders from the test packages and vessel, being certain to identify each by it's location within the load.

2. Download the data from the temperature and pressure recorders preparing time versus temperature or pressure graphs for all sensors.

3. Place all ampoules into the dry-bath incubator, noting or flagging each to identify it's location from with the test load.

4. Identify and place three unprocessed ampoules from each Lot used in the dry-bath incubator to serve as a positive control samples.

5. After 48 hours of incubation read and record the ampoule results. Yellow being a positive or "growth" result and purple or dark purple being a negative or "no growth" result.

6. If any test fails adjust manufacturer's recommended operating parameters adjust the parameters as appropriate to meet the required efficacy standard. Maintain integrity of maximum loading consistent with the specific facility's waste stream.

7. Adjustments to "cycle time" will be based upon the longest time required to achieve 250 degrees Fahrenheit temperature within any of the test packages used plus an additional "residence time" of 3 minutes for each 1 log reduction required by the efficacy standard.

8. Prepare Validation Test Report with specific operating parameter recommendations.

Validation Report
for a Medical Waste Autoclave

Testing Date / /

A. Installation Site	
Contact Name:	Title:
Facility Name:	
Address:	
City, State, Zip:	
Phone:	E-mail:

B. Equipment	
1. Equipment Information	
Manufacturer:	
Model Number:	Serial No:
Rated Capacity (lbs/hour or lbs/cycle):	
Vessel Size:	
Cart/Bin Size:	Carts/Bins per cycle:
2. Manufacturer's Recommended Operating Parameters	
Pressure Set Point:	
Temperature Set Point:	
Pre-Vacuum Yes ❑ No ❑	Vacuum Set Point:
Length of Vacuum:	Number of Pre-Vacuum Pulses:
Length of Residence Time:	
Maximum Weight Criteria Per Bin/Cart:	Per Load:

C. Regulatory Requirements	
Log Reduction of Spores:	
Organism:	
Minimum Residence Time:	
At Temperature:	At Pressure:

D. Testing Information	
1. Biological Indicators	
Manufacturer:	Type:
Lot Number:	Organism:
ATCC#:	Population:
2. Tested By:	
Name(s):	Title:
Company:	
Address:	
City, State, Zip:	
Phone:	E-mail:

E. General Description of Testing

Testing was performed in accordance with the attached protocol for waste types:

_____ _____ _____

F. Results

Use blank Results Tables as needed to record results of each Validation Cycle. Mark each set of Tables with an Exhibit Number and record below. Mark all temperature/pressure graphs for all sensors with an Exhibit Number and corresponding validation cycle and include in list below.

Exhibit Number	Description

G. Validated Operating Parameters

Type of Waste	**A** (Red Bag)	**B** (Large Sharps Container)	**C** (Suction Canister)
Cycle Time *(Not including cool down)*			
Residence Time:			
Temperature:			
Pressure:			
Number of Vacuum Pulses:			
Vacuum Set Point:			
Maximum Weight:			

NV = Not Tested or Validated

H. Recommendations

J. Attachments

Attachments Include:

I. Attested

Signature *Date*

Name: Title: Company:

Exhibit _____ Validation Cycle _____

Internal Waste Temperature Results (Graphs Attached)

	Bin Weight	Test Package Type	Recorder Number	Time to Reach 250°F	Time at 250°F	Minimum Time at 250°F for Treatment (based on D-Value)		Cycle Successful (Y or N)
						4log10	6log10	
Bin 1		A						
		B						
		Cw						
		Cs						
Bin 2		A						
		B						
		Cw						
		Cs						
Bin 3		A						
		B						
		Cw						
		Cs						
Bin 4		A						
		B						
		Cw						
		Cs						
Bin 5		A						
		B						
		Cw						
		Cs						

dnrt= Did Not Reach Temperature
Cw = Canister Containing Un-Solidified Water
Cs = Canister Containing Solidified Water
na = Not Applicable

Internal Waste Biological Indicator Results

	Bin Weight	Test Package Type	Sample Number	Sample Population	24 Hour Observation	48 Hour Observation
Bin 1		A				
		B				
		Cw				
		Cs				
Bin 2		A				
		B				
		Cw				
		Cs				
Bin 3		A				
		B				
		Cw				
		Cs				
Bin 4		A				
		B				
		Cw				
		Cs				
Bin 5		A				
		B				
		Cw				
		Cs				

G = Growth
NG = No Growth
Cw = Canister Containing Un-Solidified Water
Cs = Canister Containing Solidified Water
na = Not Applicable

Exhibit Number _____

Facility Name
Facility Location
Date
Equipment Model
Test Cycle Number

Test Cycle
3 Full Bins
Total Weight 195lbs
4.46 lbs/cuft
Residence Time ## Minutes
Total Cycle Time ## Minutes