



## WE NOW HAVE THE TECHNOLOGY! AUTOCLAVE TESTING

A PAPER PREPARED FOR THE MEMBERS OF IStAATT, MARCH 2009  
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At the onset of Regulated Medical Waste (RMW) treatment, in the mid 1980's, we had very limited technology available for the measurement of temperatures within the various layers of the waste stream. A "bundle" of thermocouple lines through a pressure vessel port was clumsy, expensive, and impracticable, but it was the "state of the art". To this day, the temperatures recorded for RMW autoclaves measure the temperature of the interstitial space between the pressure vessel shell and the waste. Such measurements generally do not reflect the temperatures within the waste and accordingly using them as a trigger for "residence times" is inappropriate.

Confronted with this reality and lacking the technology to conveniently measure the temperatures within the waste, we extrapolated our success in the operation of small laboratory autoclaves. We did this by accepting the standards codified for their treatment success and adapting them to the RMW waste stream by adding the residence time prescribed for lab units to the time the interstitial temperature took to achieve 250 degrees Fahrenheit. Listed above is a typical residence timetable. The using of such a table gave legitimacy to the practice by in concept at least of conforming to "minimum regulatory requirements." Rationally, as long as technology didn't give rise to better "science" this appeared to be an "acceptable compromise."

**Typical Current Regulations**  
**(New York State DEC Regulations 360-17; 17.5**  
**Requirements for treatment of regulated medical waste)**

| Type of Autoclave | Residence Time | Temperature | Pressure |
|-------------------|----------------|-------------|----------|
| Gravity Flow      | 60 Minutes     | 250F        | 15 PSIG  |
|                   | 45 Minutes     | 275F        | 31 PSIG  |
|                   | 30 Minutes     | 300F        | 52 PSIG  |
| Pre-Vacuum        | 45 Minutes     | 250F        | 15 PSIG  |
|                   | 30 Minutes     | 275F        | 31 PSIG  |

*Residence Time = Time at or above 250F*

From the onset, this was recognized by all as a compromise, and though practical, was not well founded in science. The testing model used in the laboratory can best be described as a "surface contamination treatment model." Comparisons between "laboratory" and "RMW" waste streams and loading characteristics "LITERALLY SCREAM" for a different approach to testing and the development of the associated machine operating parameters. The following table points out the differences.

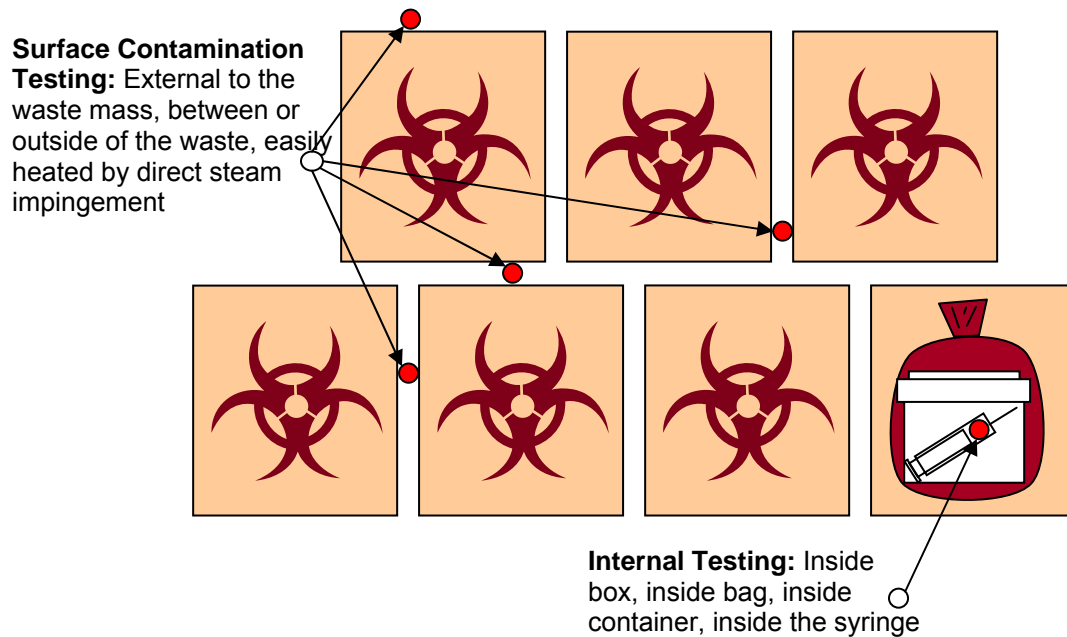
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## Testing Challenge Comparisons

| Laboratory  | Regulated Medical Waste  |
|---|--|
| Small loads, loosely distributed  | Loads up to 2,000 pounds, tightly packed   |
| No containment systems, direct steam impingement                                | Multiple containment systems introducing significant heat transfer issues                      |
| Surface contamination, non-porous material                                      | Internal contamination, porous and non-porous material   |
| Little or no liquids  | Quantities of liquids requiring long residence times (such as suction canisters)               |
| Autoclave “shell” temperature is reflective of contaminated surface temperature | Contaminated material whose internal temperature significantly lags behind “shell” temperature |

OnSite Sterilization, being a new and recent entrant to the science of autoclaves, used zero based logic, i.e. tested its autoclave units using modern technology under all circumstances and conditions to determine what machine operating parameters were actually needed to achieve various levels of log reduction. Testing was conducted using programmable data probes to find out exactly what is going on in the center of the waste – inside the box, inside the bag, inside the container, inside the syringe. The attached diagram illustrates the difference in testing techniques.

### Field Testing



## **Our testing indicates:**

### **Factors causing increased residence time requirements:**

1. Levels of Vacuum. Being labeled “a vacuum” autoclave is not adequate. Each vacuum pulse must draw at least 28 inches of mercury. This is most easily achieved with a liquid ring vacuum pump. Single stage steam ejectors generally draw less than 14 inches of mercury. Multiple stage steam ejectors can achieve higher levels of vacuum. Lower levels of vacuum leave significant amounts of air, an insulator, within the waste, which retards energy transfer and waste heating.
2. Number of Vacuum Pulses. Particularly in laboratory, 17 gallon, sharps containers multiple vacuum pulses are needed to eliminate the air in the lower strata of the container by alternately removing the air and injecting steam. Using only a single vacuum pulse significantly increases residence time requirements for large sharps containers and suction canisters.
3. Waste cross section increases residence requirements. The larger the autoclave diameter, the greater the heat transfer challenge and the longer the residence time characteristic.
4. Condensate control is essential to uniform treatment. Pooling of condensate acts as a “heat sink” that retards temperature increase in the area of pooling.
5. Liquids within the waste, such as contained in suction canisters, cause cold spots and take significantly longer to process.
6. Porous waste increases the difficulty of decontamination.
7. The larger the mass (weigh) of the waste, the longer it takes for conductivity to transfer energy to the center of the load. Residence time needs increase with greater masses.
8. Higher waste densities or compaction increase residence time needs.
9. Containerization and multiple layers of containment significantly increase residence times.

### **Factors reducing residence time requirements:**

1. Higher temperatures.
2. Continuous condensate removal.
3. Multiple vacuum pulses with greater vacuum levels.

4. Dividing the RMW stream into heat transfer challenge groups reduces average residence time by avoiding running the machinery always at “worst case” parameters.
5. The fewer the layers of containerization the better, expect shorter residence times in hospital units versus commercial units.
6. Anything that increases steam penetration reduces residence times.

**Testing indicates that the current RMW stream can be divided into three levels of heat transfer challenge.**



Each level of challenge requires additional vacuum pulses and longer residence times to affect the same level of log reduction.

Notice that achievement of the necessary level of segregation only requires a different logic in collection of RMW at the hospital. Waste routes inside the hospital would be picked up at points consistent with the heat transfer challenge, i.e. suction canisters: OR, ER, and ICU, etc.

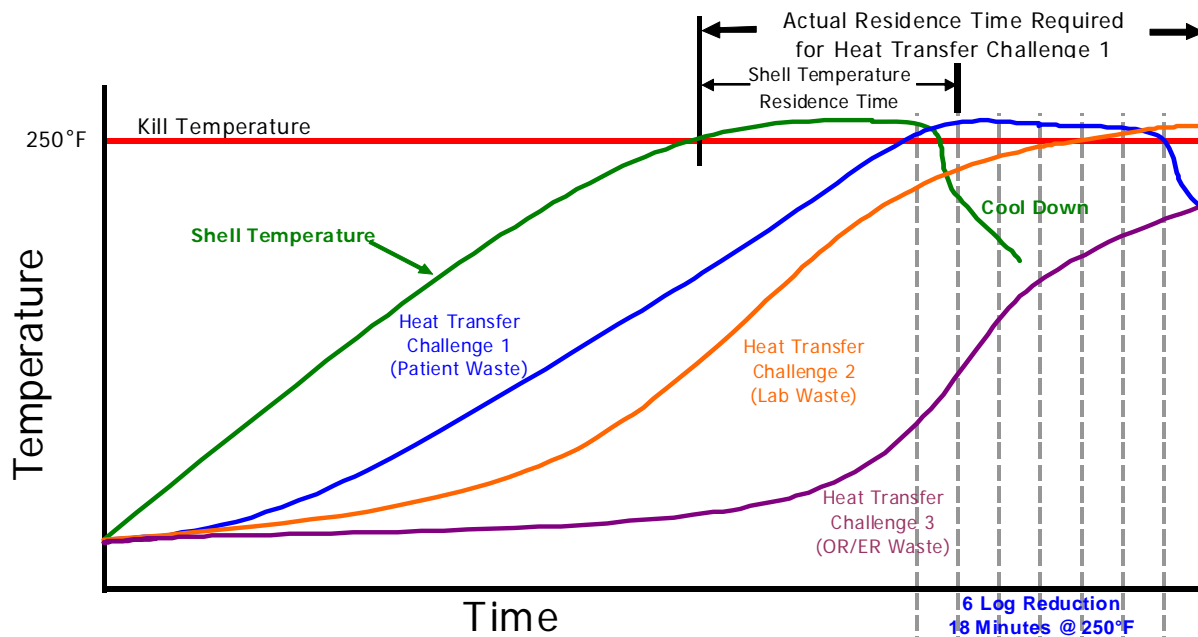
The next chart “Log reduction of spores in a Medical Waste Autoclave” demonstrates:

1. That the shell temperature which all autoclaves are currently using to trigger residence time requirements rises much faster than the internal temperature of each of the levels of heat transfer challenge.
2. That the waste associated with each level of heat transfer challenge takes a noticeably longer residence time to achieve the target 250F at the center of the waste.
3. Just reaching 250F does not necessarily achieve the desired log reduction. It takes about 3 minutes (“D” value) for every log reduction. If a six log reduction is desired, about 18 minutes at 250F in the center of the waste is

required. Suction canisters even with 3 vacuum pulses can take 6 plus hours to process, hence dividing the waste into heat transfer challenge groups is absolutely necessary to achieve acceptable production rates.

4. Notice the case of #1 heat transfer (patient waste) at a desired six log reduction, using a residence time based upon “shell temperature only” triggers shutdown and cool down just as the internal temperature reaches the 250F target. Consequently, treatment is compromised and efficacy inconsistent.

### Log Reduction of Spores in a Medical Waste Autoclave



Review of this data and the test results confirms what we have all intuitively known:

“The operating parameters of a large RMW autoclave treating large masses of heterogeneous RMW containing suction canisters, liquids, multiple containment barriers, porous and non-porous waste should not be the same as a lab unit treating non-porous steel medical devices, loosely separated and having direct steam impingement”.

We now have the necessary data collection technology [programmable, electronic data tracers]: it is accurate, relatively inexpensive, and easy to use. Considering the issues of pandemics and bio-terrorist attacks, isn't it time we got the issue of proper autoclave operating parameters behind us?

Our continued adherence to a “surface contamination testing model” albeit acceptable for laboratory autoclaves is simply inappropriate for large RMW Autoclaves as we now

have the ability to accurately determine what is happening within the waste stream as it is heated.

The challenge for us all is to develop an effective testing procedure test reporting format that is not burdensome but is sufficient to give the operator of the autoclave a set of operating parameters that gets the desired log reduction throughout the waste every time.

Attached is the protocol and validation testing format we recommend. It places the burden on the manufacturer to recommend a set of operating parameters by heat transfer challenge (or worst case analysis, suction canisters, if that course of action is elected). Validation testing, however, should be site specific. Many things can cause a need to adjust the manufacturer's recommended operating parameters.

#### Site Specific Issues:

1. Is the unit subject to changes in weather conditions (inside vs. outside, insulated pressure vessel or not).
2. The quality of steam, low quality steam with a high amount of line condensation will degrade the process.
3. Available steam flow, if steam is used to heat the hospital, will the steam flow available be less in the winter?
4. Water temperature, cooler water to the liquid ring vacuum pump will enhance vacuum pump efficiency.
5. Variances in the specific hospital's waste stream or ratio's between heat transfer challenges.

The end result will be a set of operating parameters specific to each hospital's operating characteristics and waste stream. To keep the process of iteration to a minimum, the manufacturer needs to supply valid set points for the "test stand situation" and the validation test will tailor them to the individual hospital.

#### **Note the constituents of an autoclave operating plan include:**

1. Temperature and pressure
2. Vacuum pulse plan including degree of vacuum
3. Residence time parameters for each heat transfer challenge or a single "worst case" residence time if so elected.

# 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.

# Procedure for the Validation of a Medical Waste Autoclave

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;
  - o Textiles (sheets, gauze, isolation gowns)
  - o Plastics (bottles, tubing, trays)
  - o 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;
    - o Needless syringes
    - o 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.

# Procedure for the Validation of a Medical Waste Autoclave

- 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;
  - o Textiles (sheets, gauze, isolation gowns)
  - o Plastics (bottles, tubing, trays)
  - o 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)

# Procedure for the Validation of a Medical Waste Autoclave

## **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 its 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 its location from within 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 <i>(Not including cool down)</i> |             |                            |                      |
| 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: \_\_\_\_\_

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                |                 |                     |               |  |        |                           |

*dnt= 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*

