Stericycle

LAKELAND FL OPERATING PLAN

1. Introduction:

The Lakeland Facility, 'Facility' is a processor of Regulated Medical Waste 'RMW'. RMW is processed in accordance with the provisions of F.A.C. 64E-16.007. The facility operates four Bondtech autoclave units with a total waste processing capability of 9,000 pounds/hour. The parameters of temperature and pressure of the autoclave system used at this facility are continuously monitored throughout the sterilization process. The temperature of the autoclave unit must reach at least 121 degrees Celsius (250 degrees Fahrenheit). All required records and documentation regarding operating parameters will be initialed and maintained for three years. The certification for the biological indicator to be used for the efficacy testing is attached to this Plan.

2. Inbound Waste

2.1. Medical waste received for processing is generated from hospitals, physicians' offices, blood banks, veterinary hospitals/clinics, dental practices, medical research facilities and laboratories. The types of wastes will include used sharps, contaminated PPE, tubing, gauze, surgical waste, renal dialysis waste etc.

2.2. The Lakeland Facility is the only Florida autoclave facility that has an SMS Sharps Program. All reusable sharps from SMS healthcare facilities are treated at the Facility; as a result, there is a higher percentage of syringes/sharps that are processed here.

2.3. Waste arrives at the site in bulk and non-bulk packaging on trucks/trailers. Containers/packages are removed from the vehicles and staged on the plant floor. The containers are loaded onto conveyors and move to the weigh station. Each container is weighed and scanned for billing and tracking purposes.

2.4. After the containers are weighed, they proceed down a conveyor, where they are emptied into autoclave treatment bins for subsequent transfer into the autoclave(s) for steam sterilization. Reusable empty containers are washed and sent back to our customers, while clean cardboard boxes are baled for recycling.

3. Treatment Process

3.1. When all of the treatment bins are filled and the autoclave is ready for loading, the operator opens the autoclave door and loads the bins into the autoclave. The autoclave door is closed, then the steam sterilization cycle is initiated.

3.2. A vacuum is pulled on the autoclave. The greater the vacuum the less time required to bring the unit up to operating temperature. The purpose of the vacuum is to remove the atmospheric air so the unit can attain the processing temperature quicker. The internal pressure of the boxes/bags causes them to rupture when the pressure inside the autoclave is reduced via the vacuum. This allows steam to penetrate the waste material faster and improve the treatment of the waste.

3.3. After the vacuum, steam generated from a boiler is then injected into the autoclave. The

steam will heat the waste to a minimum 250 degrees Fahrenheit during the 30 minute minimum cycle as necessary to kill geobacillus stearothermophilus. The actual operating parameters will be established for each autoclave through a validation process in accordance with the validation testing protocol.

3.4. The time required for treating the load is the sum of three components: the ramp up time, the treatment (cook) time, and the ramp down time. The ramp up time is necessary to allow the entire load to reach the optimum temperature which is accomplished by the replacement of air in the autoclave with saturated steam.

3.5. The treatment time is the minimum time at a given temperature that is known to destroy all types of microorganisms. This time is based on the thermal death of geobacillus stearothermophilus spores, which are heat resistant spores recommended for use in monitoring this treatment process.

3.6. The autoclave cycle setpoints are:
Pre-vac: 3 minutes
Ramp: 3 minutes
Soak: 15 minutes
Exhaust: 3 minutes
Post-vac: 2-3 minutes
Temperature: 292F

4. Post Treatment

4.1. Once the cycle is complete, the unit is vented through a blow down process. A vacuum is pulled to remove any excess steam in the autoclave. The unit is then brought back to atmospheric pressure and the doors are opened.

4.2. The treated waste in the autoclave bins is transferred to a compactor which then feeds into a the transfer container. 40-yard receiver box. Once full, the box is transported to a permitted landfill for final disposal.

5. QA/QC

5.1. During treatment, the following steps are taken to assure that no etiologic agents are disbursed into the environment:

5.1.1. Recording charts monitoring the time and temperature are checked throughout the cycle to verify operating standards are being met.

5.1.2. The bacteriological spore geobacillus stearothermophilus is placed in each autoclave at least once each 7 days to verify kill temperatures and time. This is a highly heat-resistant spore that is retrieved after the process and cultured in the incubator in the laboratory on site.

5.2. The spore test is conducted by placing a vial of biological indicator in PTFE tubing. The PTFE tubing is placed in the middle of the waste in an autoclave bin. After the waste is processed, the PTFE tubing is removed and the vial is placed in an incubator for 24 hours with an untreated vial as control. The chemical indicator on the processed vial will change from rose to brown indicating heat penetration. The treated vial will turn to a darker color indicating no bacterial growth. The control vial turns to yellow indicating bacterial growth.

5.3. If the spore test has growth of the spore, the load is re-processed, and the test is repeated.