MACERATOR BIOLOGICAL TESTING PROTOCOL
NOVEMBER 6, 2020

(UPDATE TO REVISION 9-DATED AUGUST 11, 2020)

MACERATOR BIOLOGICAL TESTING PROGRAM TO ENSURE 4 Log 10 (99.99%) SPORE DESTRUCTION

The Macerator reduces the size of medical waste containers to less than15 mm-50 mm. The reduced size allows for stable feeding of the Pyrolysis System, thereby producing nearly steady state syngas. Every three months the Macerator will need maintenance, therefore a Biological Testing Protocol was establish to keep the employees and the people outside the facility safe. The basic idea is to turn the Macerator into a type of “autoclave” utilizing steam, time and disinfectant.

Medrecycler-RI Macerator Sterilization

Medrecycler-RI’s general concept for disinfecting the Macerator is after a medical waste feed cycle has ended, say prior to Macerator maintenance, ten tons of non-contaminated materials will be fed to clean out as much residual matter as possible. These materials will consist of simulated medical waste (plastic, glass, paper,etc.) in cardboard boxes that contain liquid disinfectant (bleach) and lime. Clean feed will push residual matter into the Pyrolyzer and the bleach and lime will help destroy biological matter. After the clean feed is processed, bleach will be pumped into the Macerator chamber, advanced forward via the Macerator screw and allowed to operate for one hour. The screw will be put in reverse and forward to help disinfect it. After the soak time, steam will be introduced and the Macerator internal temperature will be raised to 250°F for one hour at temperature. After one hour at temperature, the steam will be shut off and Pyrolyzer shut-down will commence. Prior to entering the Macerator, a Biological Isolation Enclosure (Fig. 1) with decontamination cell will be put over the Macerator and all personnel working on the Macerator will wear Level A hazmat suits. This extra precaution is to ensure safety to employees and the environment. It may be found after several Macerator maintenance cycles, that Level B posture may be acceptable but this will be born from testing and careful review of the data.

Figure 1. Bio-Enclosure with decon-station.

To prove Medrecyclers-RI Concept and prior to feeding medical waste, a biological test will be conducted by feeding simulated wastes with biological tracers and execute a testing protocol to prove the efficacy of disinfecting the Macerator.

Macerator Indicators

Macerator indicators are devices used to check the performance of the Macerator and confirm or validate that certain performance standards have been met. The indicated used are as follows:

1. Mechanical indicators are integrated into the Macerator and record the time-temperature-pressure profile attained during decontamination cycle.

2. Biological indicators are composed of a standardized population of heat-resistant bacterial spores and Geobacillus stearothermophilus will be used to inoculate simulated medical waste. The dose of Geobacillus stearothermophilus will be determined by a profession Industrial Hygienist. They are used to determine if the sterilization cycle parameters were sufficient to kill the test microorganisms.

Macerator Waste Validations

Macerator users rely on mechanical and biological indicators and as routine verification for each Macerator maintenance cycle.

Pre-Macerator validation will follow these steps in a Pyrolyzer cold state (non-thermal load).

STEP 1: All personnel involved in the test must be trained on Macerator operation and safety.

STEP 2: Prior to turning on the Pyrolizer, A professional biological testing company, such as New England Testing Laboratory, **will sample the Pyrolizer using the appropriate and approved sample media, such as sterile swabs, the following: Macerator blades, screw, inner walls, outer walls, all the other Pyrolizer chambers surfaces and equipment the floor around the Pyrolizer, wall air vents and the inner and outer walls of the Stack. This represents the control test and all specimens taken will be put in appropriate growth media supplied by the biological testing company and they will perform culture analyses.**

STEP 3: The biological testing company will prepare 1000 pounds of simulated medical waste feed inoculated with Geobacillus stearothermophilus. Simulated medical waste by example are plastic, paper, rubber gloves, glass, chlorinated compounds like bleach and sharps. These would be sealed in standard medical waste boxes and staged for feeding into the Macerator.

Note 1: Geobacillus stearothermophilus (**GS**) will be placed in one bio-hazard bag and placed in each box of simulated medical waste. All simulated waste and all full boxes must be weighed for mass balance purposes.

Note 2: The biological testing company may have a different biological agent(s) and indicator(s) that may be suggested and justified as a change to this procedure.

STEP 4: Another 1000 pounds of simulated medical waste will be prepared without inoculation and fed after the spore containing boxes are processed. These boxes will contain bleach in plastic bottles and lime in plastic containers carefully measure by the biological testing company.

Macerator Validation Test Protocol

STEP	DESCRIPTION	COMMENTS
1	Execute Pryrolizer System Start-up Procedure	Manufacturer's Procedure
2	Verify that feed is staged and ready to feed	1000 lbs of simulated medical waste inoculated with **GS**, 1000 lbs simulated medical waste not inoculated with **GS**.
3	Heat-up Pyrolizer at a controlled rate recommended by Manufacturer	Verify and record negative pressure through the testing period
4	Heat-up such that the Thermal Oxidizer reaches 1,500°F and Pyrolizer reached 1,600°F, and is maintain these temperatures for 1 hour or until reasonable steady state condition.	Verify and record negative pressure through the testing period
5	Once Thermal Oxidizer and Pyrolyzer are at their steady state temperatures, start feeding simulated medical waste containing spore vials.	Record start and stop times, determine feed rate.
6	At the same feed rate of the **GS** feed, start feeding the simulated medical waste that is not inoculated.	Record start and stop times, determine feed rate.
7	Once feeding has been completed the Pyrolyzer System will operate during the Macerator Disinfect Phase	Record end of feed
8	Inject bleach into the Macerator and operate it such that the bleach stays in the Macerator for 1 hour without feeding into the Pyrolizer.	Amount of bleach will be determined by the biological testing company
9	After 1 hour, feed 100 pounds of boxes containing lime and plastic .	Use only lime, CaO (alkaline)and not Lime Away (acidic; reaction with bleach will generate chlorine gas)
10	After lime and plastic feed, inject steam and raise the temperature of the Macerator to 250°F an hold for one hours at temperature.	Ports used for steam injection should allow for even heating.
11	After steam injection time, start cool-down of Pyrolizer System	This will take several days or a week to accomplish.
12	Once the Pyrolizer System has reached Ambient temperature and prior to **Macerator Enclosure**, **Sample the Pyrolizer using the appropriate and approved sample media, such as sterile swabs, the following: Macerator, Pyrolizer, all other equipment surfaces and the floor around the Macerator and Pyrolizer, wall air vents and the inner and outer walls of the Stack. Once sampling is completed,** put Macerator Enclosure into position	
13	Wearing Level A hazmat suits, personnel enter the enclosure. The enclosure will remain in place until validation by the biological testing company.	Level A suits will be samples by the biological testing company prior to dawning them.They will go through decon-cell first.
14	The Macerator is then opened, outer panels removed and **sample the Pyrolizer using the appropriate and approved sample media, such as sterile swabs, the following: All Macerator blades, screw, inner walls and outer walls. All the other chambers surfaces and equipment, the floor around the Macerator Pyrolizer, wall air vents and the inner and outer walls of the Stack.**	
15	Before removing the Level A suits, the suits will be sampled. Personnel will deco-con and then remove Level A suits.	
16	All specimens taken will be put in appropriate growth media	All of this is to ensure 4 Log 10 or

	supplied by the biological testing company and they will perform culture analyses at their facility.	99.99% destruction of spores.

Interpreting the Results

GS Inoculation: All sampled post cool-down swabs or other media should exhibit no growth or at least 99.99% destruction in the media selected of the test species. The control samples and post test samples should be reasonably the same except for the Macerator; the cultures of background organism should be much reduced. If spore growth of the test species is exhibited in any culture, the Pyrolysis Validation has failed to sterilize the load and the test must be repeated except **GS** inoculated simulated medical waste will not be fed.

Validation of Macerator Sterilization means no growth or at least 99.99% destruction of any cultured media of the test species.

Reporting Results

Biological testing company will produce a report and copies will be given to RIDEM and Medrecycle-RI. RIDEM and Medrecycler-RI will meet with the biological testing company to verify results. This testing program will produce a firm sterilization plan for the Macerator and thereby establish the **Macerator.**

Scheduled Testing

Once operational with a firm sterilization plan, the Macerator shall be tested every 40 hours of operation.