EPA Permitting: An Autoclave's Journey

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Introduction

Biomedical waste is primarily regulated by state environmental and health departments. In Ohio, disposal of infectious waste (IW) is regulated by the Ohio Environmental Protection Agency (EPA) and monitored by the City of Cleveland Department of Health. Their main priority is to ensure landfills are free of contaminated materials thus eliminating negative impacts on the environment such as spread of disease or air/water pollution.

Our facility is considered a 'large generator' of IW as per Ohio EPA guidelines. Specifically we are large generators (>50lbs per month) of ABSL2 'rodent bedding' that is being disposed of to local landfills. While our standard operating procedures (SOPs) included autoclaving all IW out of our ABSL2 facilities for disposal to landfills, or shipping all PPE, carcasses and bodily fluid waste to Stericycle for incineration (Figure 1), the Ohio EPA and Cleveland Department of Health shut down our IW processing via regular trash disposal in late 2023 due to compliance concerns. During the shutdown, we were able to autoclave and dump cages in our facility, box the IW, and either send it to Stericycle for incineration or send it to our institution's Ohio EPA registered roto-clave facility for disposal. Concurrently, validation testing was performed and the proper documents in the preferred format for the Ohio EPA and Department of Health were being generated.

Objectives

The objective of this poster is to describe the process for obtaining a permit to become a 'large generator' facility for the handling of IW and detailing the documentation required by the Ohio EPA to maintain this permit.

Waste Disposal in the BRU

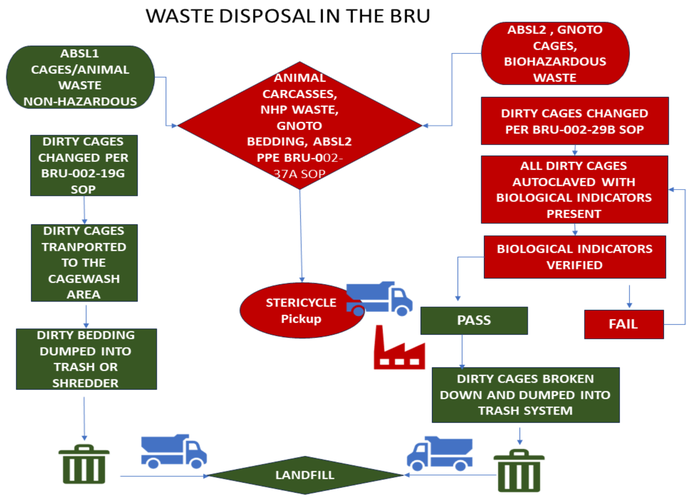

FIGURE 1: Schematic depicting the processing of all IW across all our facilities

Process

Prior to 2024, biological indicator (BI) tests (MesaLabs – EZTest® and Releasat®) and chemical temperature strips were processed in clean cages for both our dry heat and steam sterilizers. These tests are run to confirm that the autoclaves are reaching proper temperatures and pressures required to kill the infectious materials. As part of our facility SOPs, these tests were completed each month and documented.

For the validation process required by the Ohio EPA, multiple test cycles were run to demonstrate that our systems met the Ohio EPA performance standards. Performance verification included documenting; (1) testing waste load and amount, (2) the BI's and chemical temperature strips for each run, (2) autoclave maps and sterilizer cycle run data printouts, (3) calibration certifications that must be performed annually, and (4) facility SOPs, contingency plan and emergency contact plan. The initial validation required incubation of the BI spore tests for 7 days to ensure that spores were killed during the cycle. After obtaining EPA approval, BI tests are now run per the manufacture's specifications (24h).

Validation documentation was required for each system and each set of autoclave cycle parameters. Once the spore tests were confirmed negative for a cycle, cages could be processed via normal procedures in cage wash.

CURRENT PROCESS & REQUIRED DOCUMENTATION:

For every IW autoclave cycle, a map of cage locations, a printed copy of the autoclave cycle tape containing the time, temperature and pressure through the entire run and the chemical temperature strip must be maintained. The tape and chemical strip are attached to the map and added to the documentation notebook (Figure 2).

Each month, we must run the cycle with BI's inserted into the dirty cages. These tubes are removed and incubated for 24 hours with a control tube that has not been autoclaved. The control tube will turn yellow while the autoclaved tubes will remain purple indicating the bacteria in the tube has been destroyed in the process. A photo is stored electronically and printed.

A notebook is maintained that the Cleveland Department of Health currently checks every 2 weeks post approval. After 90 days, the Department of Health will complete random reviews of the records on a quarterly basis. The notebook contains the map, BI photos, chem temp strip and autoclave print out for each run. It also contains the new protocols we have created and a list of phone numbers to contact in case of an accidental spill. We are required to keep these documents for 3 years in hard copy or digital format.

TABLE 1: Dry heat and steam parameters for our facility sterilizer systems.

Autoclave	Model	Temperature	Pressure	Sterilization Time
Primus Sterilizer (Steam)	Pri-Matic 200 PSS9	121 C	15 PSI	20 minutes
Steris Autoclave (Steam) Cycle	Amsco Century SV-148S Prevac	132 C	28 PSI	4 minutes
Steris Autoclave (Steam) Cycle	Amsco Century SV-148S Cages	133 C	27 PSI	15 minutes
Grueberg Dry Heat Sterilizer	Steri-Dry Class B	285 C	NA	140 minutes

Autoclave Parameters

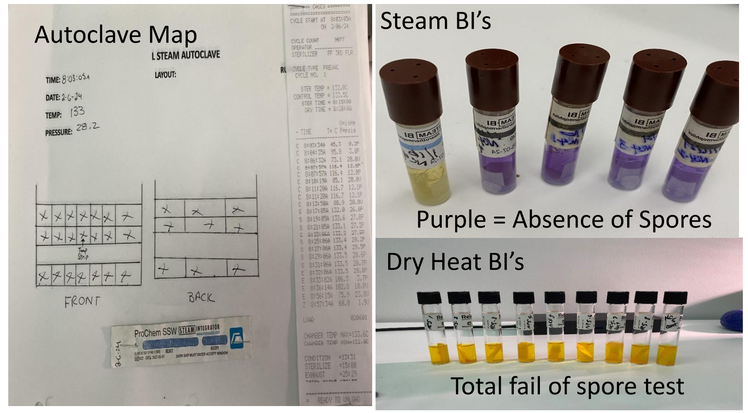

FIGURE 2: Representative images of the autoclave map and printout strip required (left panel) and failed and successful steam and dry heat BIs (right panel).

Conclusion

Through this validation process, we learned that our normal dry heat cycles (Table 1) did not adequately kill the spores (Figure 2) during the processing of dirty cages as we had previously assumed. While the chemical temperature strips showed that temperatures reach the goal, our BI results revealed that the dry heat did not permeate adequately through the bagged cages containing water-logged bedding and debris. The cages did not reach the correct interior temperature required for the sustained period to kill the bacteria spores. We also learned that the Ohio EPA currently has no guidelines for using dry heat autoclaves to process IW. Approved treatment methods include (1) incineration, (2) autoclaving (steam), (3) chemical treatment utilizing a sodium hypochlorite solution (cultures), (4) applied heat encapsulation (sharps), and (5) chemical treatment utilizing peracetic acid/grinding. Thus, all facility IW processing is now done in the steam heat autoclaves.

Ultimately, much of the testing the EPA required was already being done. While we did test monthly to ensure that our systems were working properly our inefficiencies were in maintaining the proper documentation as per Ohio EPA requirements.

We are continuing to work with the EPA to find a successful way to utilize the dry heat sterilizer to process IW as well as maintain the validation for the steam autoclaves.

REFERENCES

Rule 3745-27-32 Standards for the Operation of Infectious Waste Treatment Facilities, Ohio Administrative Code/3745/Chapter 3745-27 | Solid Waste and Infectious Waste Regulations. https://codes.ohio.gov/ohio-administrative-code/chapter-3745-27

Amsco Century Medium Steam Sterilizer Operator Manual

18975 PRI-Matic 200 PSS9 Operator Manual