

# DESIGN AND VALIDATION OF A MODIFIED TRANSFER CASE FOR HIGH RISK WASTE PROCESSED BY THERMAL DECONTAMINATION

Rachel Smith, Wendy Kilthau, Bobby Parchuri, and Fahim Manzur, Arctic Slope Regional Corporation Federal Field Services  
 Geoffrey Ferman, Department of Homeland Security, Science and Technology Directorate, Plum Island Animal Disease Center

### Scope

- Design and validate the efficacy of a modified transfer case (MTC), primarily for waste removal, when used in a Class III Biosafety Cabinet (BSC). The MTC will remain fully sealed until it has been removed from the BSC and thermally decontaminated by autoclaving.
- Developing a MTC is crucial to operation of a Class III BSC where an integrated autoclave is not possible.

### Objectives

- Design a MTC capable of steam penetration for microbial decontamination while maintaining isolation of contents until the melt temperature of the seal is achieved.
- Verify a temperature sensitive seal that will allow for steam penetration and pressure equalization between the autoclave chamber and the interior of the MTC.
- Validate the microbiological decontamination efficacy when autoclaving microbial waste contained within the MTC.

### Methods

- The lid of the MTC was designed with replaceable paraffin wax plugs that melt during the autoclave cycle to allow for steam penetration and pressure equalization.
- Commercially available self-contained biological indicators (SCBIs) were used to validate the decontamination process through appropriate placement in the mock waste material.
- Thermal profile data was obtained through thermocouple data-loggers placed inside each MTC and on the autoclave rack.

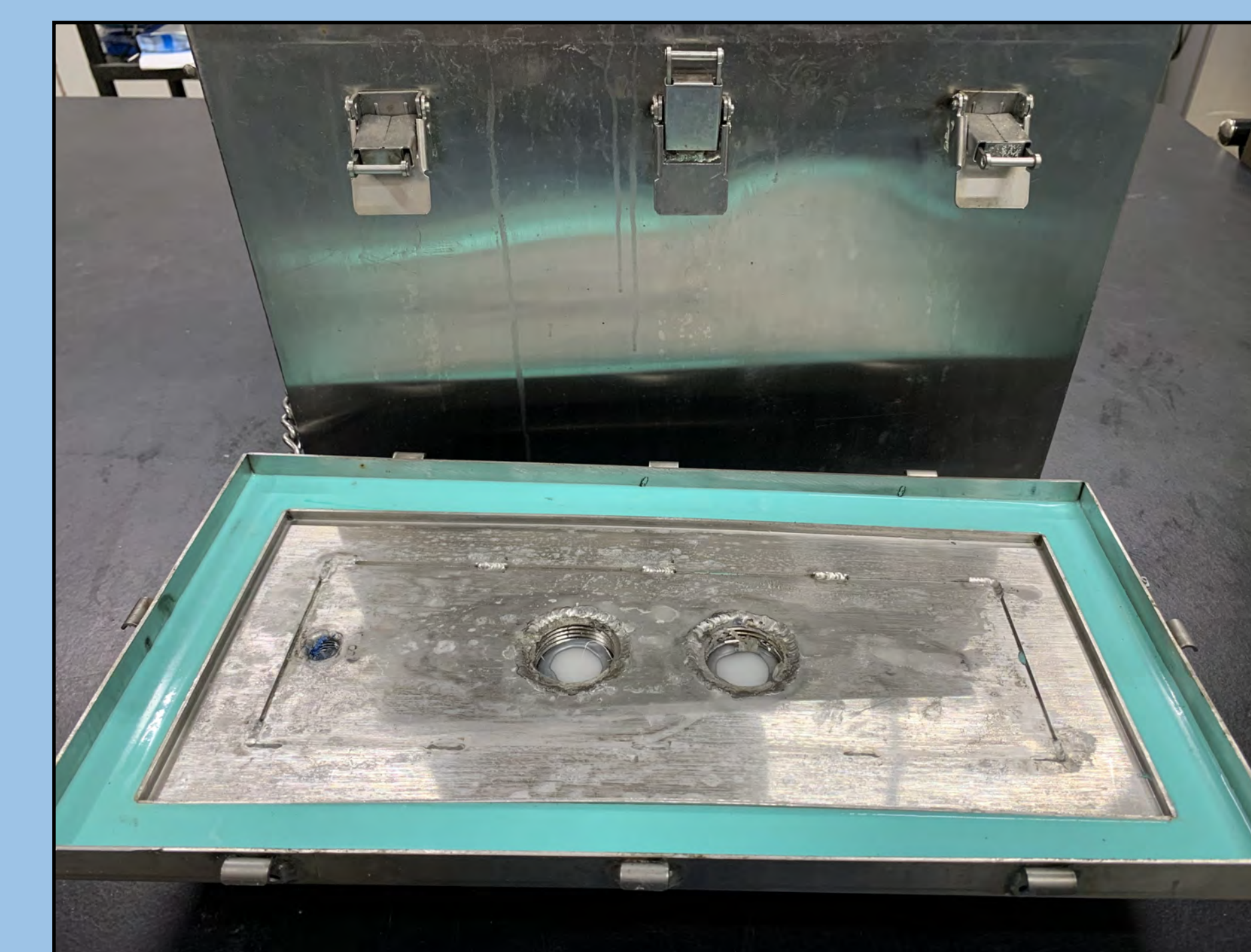
## Modified Transfer Case (MTC) with Paraffin Wax Plugs



Paraffin wax plugs with threads wrapped in Teflon tape are designed to temporarily seal the MTC at room temperature until the melt point, ~100-150°F (~37-66°C), is reached during the autoclave cycle. The plugs are reusable when refilled with paraffin wax.



MTC with two threaded openings for reusable paraffin wax plugs to be inserted. The MTC is able to be closed and form an airtight seal (verified via pressure testing).



The MTC lid is fitted with a gasket to ensure an airtight seal (verified via pressure testing) when fitted with the reusable paraffin wax plugs.

## Load Contents

### Initial Melt Test



A MTC for the initial melt test contained an autoclave pouch with 3 SCBIs as well as a pouch with 2 data-loggers.

The MTC was placed inside the autoclave alongside an autoclave pouch containing 2 data-loggers to baseline chamber temperature.

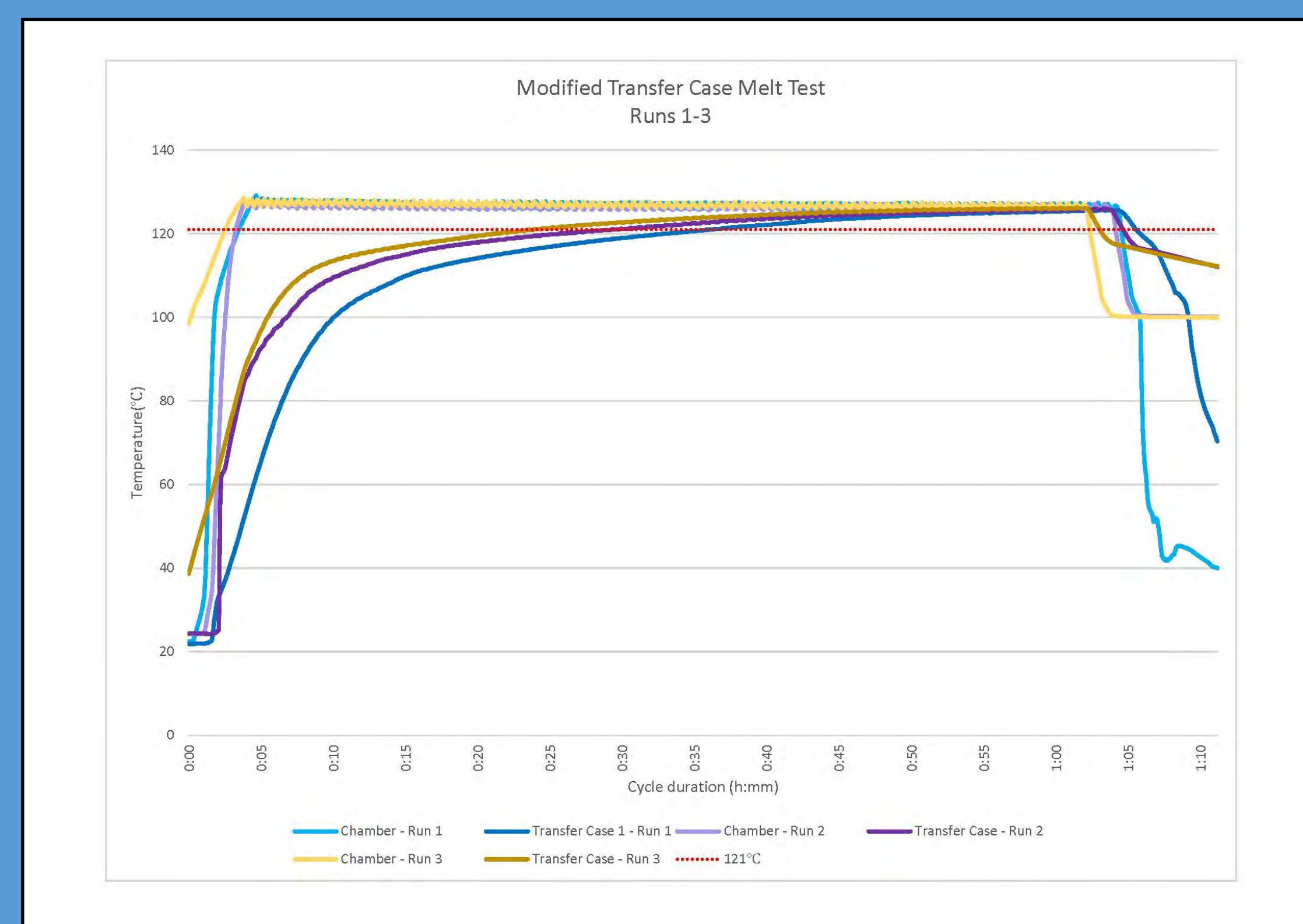
### Mock Waste Test



Representative mock waste used to obtain a thermal profile included snap cap vials, KimWipes, pipette tips and conical tubes.

Representative mock laboratory waste used to obtain a thermal profile. The "hanger" bag also contained an autoclave pouch with 3 SCBIs and a pouch with 2 data-loggers.

## MTC Thermal Profiles



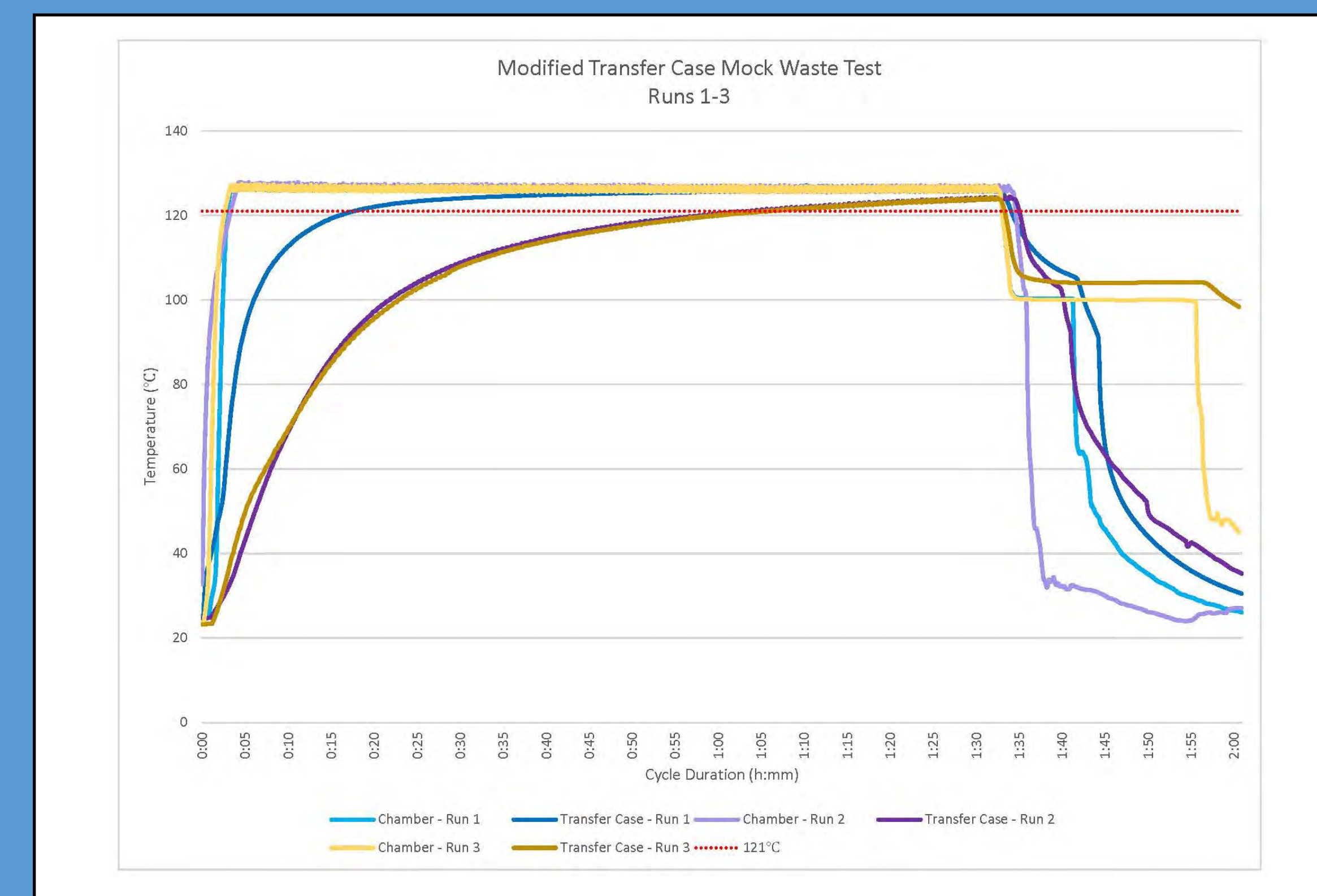
Thermal profile obtained from temperature data-loggers in an empty MTC. Graph depicts adequate contact time for paraffin wax plugs to melt and thermal inactivation of the SCBIs within the MTC.

Melt Test Validation Test	Time at 121°C (hh:mm)	Biological Indicator Results
Run 1	Chamber: 01:01 Load: 00:29	Pass
Run 2	Chamber: 01:00 Load: 00:35	Pass
Run 3	Chamber: 00:59 Load: 00:39	Pass

Cycle parameters: Gravity Cycle, 121°C, 60 minutes

### Mesa Labs EZ Test Biological Indicator Data

*Geobacillus Stearothermophilus* 7953  
 Population:  $2.1 \times 10^8$  CFU  
 COA Specs (Steam @ 121°C)  
 D-Value: 2.0 min  
 Kill Time: 20.70 min



Thermal profile obtained from temperature data-loggers in a MTC containing mock waste. Graph depicts adequate contact time for paraffin wax plugs to melt and thermal inactivation of the SCBIs within the mock waste load within the MTC.

Mock Waste Validation Testing	Time at 121°C (hh:mm)	Biological Indicator Results
Run 1	Chamber: 01:30 Load: 00:57	Pass
Run 2	Chamber: 01:31 Load: 00:30	Pass
Run 3	Chamber: 01:30 Load: 00:28	Pass

Cycle Parameters: Gravity cycle, 121°C, 90 minutes

## Class III Biosafety Cabinet: "Glovebox"



A Class III Biosafety Cabinet is designed to keep its contents completely sealed from the external environment. When an integrated autoclave is not possible, a modified transfer case can be used to contain any waste materials until the cabinet interior has been decontaminated and the transfer case has been removed and autoclaved.

### Results

- A MTC with replaceable paraffin wax plugs will unseal and allow steam penetration after reaching the melting point of the paraffin wax within an autoclave, while remaining sealed at room temperature.
- All test SCBIs demonstrated no growth when autoclaved with mock waste. Control SCBIs performed as expected. Testing showed consistent and repeatable inactivation of SCBIs within the mock waste when autoclaved at 121°C for 90 minutes.
- All SCBIs demonstrated no growth in all test samples, all integrators demonstrated acceptable time/temperature exposure and data-loggers recorded acceptable temperature profiles based on the D-values of the SCBIs.
- Consistent and repeatable biological inactivation of the SCBIs was verified through performance of triplicate runs and consistent thermal profiles.

### Conclusion/Outcome

Effective use of the MTC is critical to waste material management for the Class III Biosafety Cabinet (with no integrated autoclave). Using paraffin wax plugs allows for a testable airtight seal isolating the waste until the MTC has reached the paraffin wax plug melting point in the autoclave. In order to effectively decontaminate the contents of the MTC at the autoclave gravity cycle temperature of 121°C the dwell time was increased from 60 minutes to 90 minutes. These parameters ensured steam penetration and biological in-activation (biological indicator kill) of the mock waste.

### Acknowledgements

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