



REPORT NO: 15/0147

**EFFICACY TESTING OF ONE HOT OIL DISINFESCTION UNIT
SYSTEM TO DEMONSTRATE COMPLIANCE WITH ENVIRONMENT
AGENCY LISCENCE NUMBER: EPR/WP3636ZG**

Premises: Tradebe Healthcare

Location: Wrexham treatment facility

Dates: 5th August 2015

Consultants: M Wadie
A Bailey

CLIENT	REPORTED BY
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August 2015	
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EXECUTIVE SUMMARY

Tradebe Healthcare Ltd commissioned Industrial Safety Solutions to undertake a re-validation assessment of the efficacy of one Hot Oil Disinfection Unit (HDU) system located at their Wrexham Treatment Facility. The re-validation was requisite to meet the 48 month testing requirement as stated in EPR5.07 version 1.1 and follows on from the plant fail identified in the previous testing.

Tradebe have serviced the HDU plant, removed a large core of plastics that had melted to the hollowflights and have also introduced a spray system to provide a consistent source of moisture and hence steam in the process.

The results of Efficacy testing, using the nominated Biological Indicator Species of 6 Log₁₀ *Bacillus atrophaeus* with a D-Value of 1.9, show that a >4 Log₁₀ inactivation has been achieved for 100% samples, therefore STAATT level III criteria have been achieved.

Statistical Analysis of the data and recovery of the control samples demonstrates that the minimum standards of Log (XC-4) $\geq$ LogLu and Log Xc must be $\geq$ 5, (Log Xc= 6.0, Log (XC-4) =1.77 and LogLu= 1.35) have been achieved, therefore it is >97.5% probable that any waste suitable for treatment in alternative technologies, will be treated to the minimum standard.

The recovery of all Biological Indicator spores from the control strips was well within the US Pharmacopeia standard for biological indicators.

Thermal test strips (Raven Laboratories Pro Chem. EXT, (7min@135°C/ 20 min @121°C) recovered from the destroyed rocket canisters showed that the temperature requirements had been met.

1. INTRODUCTION

Tradebe Healthcare Ltd commissioned Industrial Safety Solutions to undertake an assessment of the efficacy of one Hot Oil Disinfection Unit (HDU system located at their Wrexham, Clinical Waste Treatment Facility. The re-validation was requisite to meet the 48 month testing requirement as stated in EPR5.07 version 1.1

This report presents the findings of the survey conducted in August 2015.

This monitoring is deemed requisite to comply with the strictures within the Environment Agency Permit Number: EPR/WP3636ZG

2. OBJECTIVE

The objective of the survey is to demonstrate the efficacy of rendering medical waste safe by one Hot Oil Disinfection Unit. The efficacy testing is to comply with State and Territorial Association on Alternative Treatment Technologies (STAATT) Level III, as defined in Environment Agency Document EPR 5.07 version 1.1 January 2011

This defines the monitoring requirements, to which this Specification Document aims to satisfy. One key requirement of STAATT Level III is to prove a $4\log_{10}$ inactivation of thermo-resistant indicator spores, those being either *Geobacillus stearothermophilus* or *Bacillus atrophaeus*, in a worst case scenario challenge load.

It is recognised that emissions from technically sound clinical waste treatment plants, operated under good practice with appropriate containment, and treating appropriate waste should be low.

Where waste acceptance or pre-acceptance procedures are poor, and/or containment is inadequate or unproven, this assumption cannot be made. The onus is therefore on the operator to demonstrate that emissions from the plant are controlled during both commissioning and more importantly during routine operation.

Microbial monitoring is required, as there is the potential for aerosols containing pathogenic organisms to be released during the operation of alternative waste treatment plants.

Potential sources include:

- During maceration of untreated clinical waste
- The release of exhaust gases
- During maceration of treated clinical waste
- Failures in plant integrity
- During the washing of waste bins which may contain untreated biological residues from spillages/splits in waste bags

3. PROCESS DESCRIPTION

The installation features one HDU auger, which processes an average of 800kg per hour.

The waste treatment process involves the following discrete process stages:

The waste is weighed and then the bins are lifted and tipped into the macerator. Air from the infeed hopper is drawn by fans through a series of filters including a High Efficiency Particulate Air (HEPA) filter and a carbon filter to control odours

Waste is then picked up by a stainless steel screw conveyor, and fed into a high temperature Auger with a jacket heated via hot oil.

The entire process is controlled by microprocessors which monitors the waste treatment cycle, assuring that all time and temperature parameters required for treatment are met before any waste is discharged.

The waste is then transferred via screw conveyor into a compactor for final disposal to landfill

It should be noted that there are no external discharges to atmosphere as after filtration the air is re-circulated into the workplace.

In addition there is no discharge to sewer as any steam input is held in the pulpable mass of the waste and discharged into the compactor.

The result will be sterilisation of all processed materials which, as a minimum, aim to satisfy Level III of the State and Territorial Association on Alternate Treatment Technologies (STAATT) standards for clinical waste treatment (i.e. a 4log₁₀ inactivation of the microbial population of the waste).

4. PROCEDURES

Due to the process parameters the efficacy testing was carried out using *Bacillus atrophaeus* as the indicator species.

Three tests cycles of the HDU were undertaken via the introduction of tennis balls loaded with the Biological Indicators. Due to the pre maceration of waste, the tennis balls are loaded into the process via an access hatch in the feed chute into the system just before the treatment system and steam input.

The BI system comprised of a MESA Biological Laboratories spore strip inoculated with 6log₁₀ of *Bacillus atrophaeus* in a permeable glassine paper pouch and a D-Value greater than 1.8

Three tests cycles for the HDU were undertaken via the spore strips attached to tennis balls to ensure safe passage through the auger systems without sample loss

To meet the sample recovery requirements given in EPR 5.07 Version 1.1, 15 samples canisters were loaded per cycle, to ensure sufficient sample recovery (10 required to be collected)

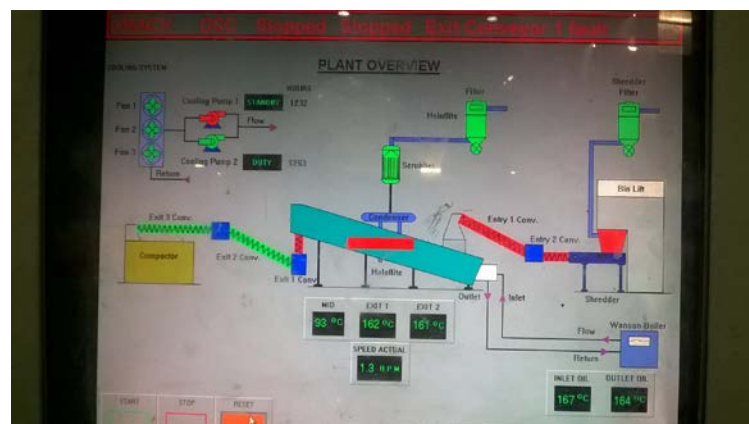
In line with Environment Agency guidance all biological Indicators will be selected to have a minimum D- Value of 1.8

5. PROCESS CONDITONS AND OBSERVATIONS

All waste used during testing was unselected and as such provides a representative sample of the waste types processed by Tradebe Healthcare Ltd.

All samples that were recovered in excess of the sampling requirements were sent for analysis in line with the guidance in EPR 5.07 version 1.1 January 2011

The plant had undergone maintenance and repair and all of the holloflights were clear of plastics (which had formed a potential thermal barrier) and were working correctly at temperature.



In addition a spray system had been introduced to the plant to ensure a steady moisture content of the waste to give a uniform steam distribution in the HDU and to assist in the transmission of heat throughout the waste.

The collection of samples from each test run was sufficient to ensure that the number of spore strips recovered met the requirements of the testing protocol.

6. RESULTS TABLES

HDU TEST 1

Sample Reference	Batch/Lot number	Carrier Type	Container Recovered YES/NO	Sample Recovered YES/NO	Steam Strip Recovered YES/NO	Steam Strip PASS/FAIL	Log ₁₀ inactivation
1.1	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.2	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.3	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.4	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.5	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.6	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.7	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.8	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.9	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.10	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.11	BATR-425	Tennis ball	YES	YES	YES	Pass	6
1.12	BATR-425	Tennis ball	YES	YES	YES	Pass	6

HDU TEST 2

Sample Reference	Batch/Lot number	Container Type	Container Recovered YES/NO	Sample Recovered YES/NO	Steam Strip Recovered YES/NO	Steam Strip PASS/FAIL	Log ₁₀ inactivation
2.1	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.2	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.3	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.4	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.5	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.6	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.7	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.8	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.9	BATR-425	Tennis ball	YES	YES	YES	Pass	5
2.10	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.11	BATR-425	Tennis ball	YES	YES	YES	Pass	6
2.12	BATR-425	Tennis ball	YES	YES	YES	Pass	5

HDU TEST 3

Sample Reference	Batch/Lot number	Container Type	Container Recovered YES/NO	Sample Recovered YES/NO	Steam Strip Recovered YES/NO	Steam Strip PASS/FAIL	Log ₁₀ inactivation
3.1	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.2	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.3	BATR-425	Tennis ball	YES	YES	YES	Pass	5
3.4	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.5	BATR-425	Tennis ball	YES	YES	YES	Pass	5
3.6	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.7	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.8	BATR-425	Tennis ball	YES	YES	YES	Pass	4
3.9	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.10	BATR-425	Tennis ball	YES	YES	YES	Pass	4
3.11	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.12	BATR-425	Tennis ball	YES	YES	YES	Pass	6
3.13	BATR-425	Tennis ball	YES	YES	YES	Pass	6

7. DISCUSSION OF RESULTS AND CONCLUSION

Tradebe Healthcare Ltd commissioned Industrial Safety Solutions to undertake a re-validation assessment of the efficacy of one Hot Oil Disinfection Unit (HDU) system located at their Wrexham Treatment Facility. The re-validation was requisite to meet the 48 month testing requirement as stated in EPR5.07 version 1.1 and follows on from the plant fail identified in the previous testing.

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APPENDIX 1

CERTIFICATION FOR BIOLOGICAL INDICATORS

MESASTRIP

BIOLOGICAL INDICATOR
For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No.: SGMG/6

Bacillus atrophaeus 9372⁽¹⁾

Biological Indicator for: Ethylene Oxide / Dry Heat Sterilization.

Culture: Soybean casein digest broth

Purity: No evidence of contaminants using standard plate count techniques.

Lot No.: **BATR-425** Manufacture Date: 2015 February 17

Expiration: 2017 February 17

Heat Shocked Population: 3.5×10^6 Spores / Unit

Carrier Size: 1" x 1/4" (25 mm x 6 mm)

Assayed Resistance:

	D-Value ⁽²⁾	Survival ⁽³⁾	Kill ⁽³⁾	
Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C) 100% EtO	3.1	14.31	33.21	min
Dry Heat (160°C) ⁽⁴⁾	2.1	9.51	22.07	min
Z-value: 46.1°C				

D-value reproducible only when exposed in an AAMI BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with Mesa Laboratories' quality standards, USP, ISO 11138 guidelines, and all appropriate subsections.

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

⁽²⁾ D-value calculated using the Limited-Holcomb-Spearman-Kärber method.

⁽³⁾ Survival/Kill values are calculated according to USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation.

⁽⁴⁾ Oxyfume 2000 is a registered trademark of Honeywell.

⁽⁵⁾ With exception to D₁₀₀-value specified in ISO 11138-4.

Certified By:

Quality Representative

Complete Quality Control testing results available upon request.



Bozeman Manufacturing Facility
10 Evergreen Drive
Bozeman, MT 59715
T: 303/987-8000 • F: 406/585-9219
www.mesalabs.com

APPENDIX 2 LABORATORY ANALYSIS CERTIFICATION



Industrial Safety Solutions
MH2 Building, Unit 26A
Parkhall Business Park
Longton
Stoke-On-Trent,
Staffordshire
ST3 5XA

Sample Description: WREXHAM

Matrix Type: STRIPS

Certificate of Analysis

Certificate ID: 2015-000034800/ 0

Sample Date: 05/08/2015
Sample Received: 07/08/2015
Analysis Commenced: 07/08/2015
Analysis Complete: 12/08/2015
Order Number: 15/0147
Batch Number: 1508000103

Laboratory No.	Sample Name	Sample No.	Bacillus Atrophaceus cfu/strip
2015-000034800	RUN 1 SAMPLE 1	1	<1
2015-000034801	RUN 1 SAMPLE 2	2	<1
2015-000034802	RUN 1 SAMPLE 3	3	<1
2015-000034803	RUN 1 SAMPLE 4	4	<1
2015-000034804	RUN 1 SAMPLE 5	5	1
2015-000034805	RUN 1 SAMPLE 6	6	<1
2015-000034806	RUN 1 SAMPLE 7	7	<1
2015-000034807	RUN 1 SAMPLE 8	8	<1
2015-000034808	RUN 1 SAMPLE 9	9	<1
2015-000034809	RUN 1 SAMPLE 10	10	<1
2015-000034810	RUN 1 SAMPLE 11	11	<1

Samples outside recommended time frame from sampling to analysis - validity of results may be affected.

Approved By

Sonal Patel (Operations Manager)
12/08/2015

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Industrial Safety Solutions
MH2 Building, Unit 26A
Parkhall Business Park
Longton
Stoke-On-Trent,
Staffordshire
ST3 5XA

Sample Description: WREXHAM

Matrix Type: STRIPS

Certificate ID: 2015-000034812/ 0

Certificate of Analysis

Sample Date: 05/08/2015
Sample Received: 07/08/2015
Analysis Commenced: 07/08/2015
Analysis Complete: 12/08/2015
Order Number: 15/0147
Batch Number: 1508000103-1

Laboratory No.	Sample Name	Sample No.	Bacillus Atrophaeus cfu/strip
2015-000034812	RUN 2 SAMPLE 1	1	<1
2015-000034813	RUN 2 SAMPLE 2	2	1
2015-000034814	RUN 2 SAMPLE 3	3	<1
2015-000034815	RUN 2 SAMPLE 4	4	<1
2015-000034816	RUN 2 SAMPLE 5	5	<1
2015-000034817	RUN 2 SAMPLE 6	6	<1
2015-000034818	RUN 2 SAMPLE 7	7	NA
2015-000034819	RUN 2 SAMPLE 8	8	10
2015-000034820	RUN 2 SAMPLE 9	9	<1
2015-000034821	RUN 2 SAMPLE 10	10	<1
2015-000034822	RUN 2 SAMPLE 11	11	3

Samples outside recommended time frame from sampling to analysis - validity of results may be affected.

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Industrial Safety Solutions
MH2 Building, Unit 26A
Parkhall Business Park
Longton
Stoke-On-Trent,
Staffordshire
ST3 5XA

Sample Description: WREXHAM

Matrix Type: STRIPS

Certificate of Analysis

Certificate ID: 2015-000034824/ 0

Sample Date: 05/08/2015
Sample Received: 07/08/2015
Analysis Commenced: 07/08/2015
Analysis Complete: 12/08/2015
Order Number: 15/0147
Batch Number: 1508000103-2

			Bacillus Atrophaceus cfu/strip
Laboratory No.	Sample Name	Sample No.	*
2015-000034824	RUN 3 SAMPLE 1	1	<1
2015-000034825	RUN 3 SAMPLE 2	2	<1
2015-000034826	RUN 3 SAMPLE 3	3	<1
2015-000034827	RUN 3 SAMPLE 4	4	5
2015-000034828	RUN 3 SAMPLE 5	5	1
2015-000034829	RUN 3 SAMPLE 6	6	<1
2015-000034830	RUN 3 SAMPLE 7	7	<1
2015-000034831	RUN 3 SAMPLE 8	8	<1
2015-000034832	RUN 3 SAMPLE 9	9	<1
2015-000034833	RUN 3 SAMPLE 10	10	32
2015-000034834	RUN 3 SAMPLE 11	11	<1

Samples outside recommended time frame from sampling to analysis - validity of results may be affected.

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