Clinical Waste Treatment
Commissioning, Validation & Efficacy Testing
Best Practice Guide

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## 1. INTRODUCTION

This best practice guide aims to bring together the knowledge from members of the Healthcare Waste Management Association, including the Waste Treatment companies, consultants, microbiologists, and the Laboratories involved in the commissioning, validation, and routine testing for alternative treatment technologies in the UK. Alternative Treatment (AT) is defined in the Environment Agency (EA) guidance document "Healthcare waste, appropriate measure for permitted facilities" and Scottish Environment Protection Agency (SEPA) document "Guidance for the Storage and Treatment of Healthcare Waste".

The information provided within is by no means definitive but provides the most reasonably practicable approach to achieve compliance with regulation, based on the commercially available technologies and biological indicators at the time of writing.

It should be read in conjunction with Environment Agency (EA) guidance document or Scottish Environment Protection Agency (SEPA) document, both referenced above and available at the following links:

- Healthcare waste: appropriate measures for permitted facilities - Guidance - GOV.UK (www.gov.uk)
- guidance-for-the-storage-and-treatment-of-healthcare-waste.pdf (sepa.org.uk)

It should also be read in conjunction with the environmental permit for the alternative treatment plant. The regulator will enforce the requirements of the aforementioned guidance through the operators permit. The permit will include a pre-operational condition requiring the commissioning and validation to be carried out, then reported to and approved by the regulator prior to the operation of any new plant. Prior to undertaking the commissioning tests, written proposals detailing the commissioning tests that will be carried out should be sent to the regulator (local area officer) for written agreement before the tests are undertaken. The permit will also include conditions requiring routine efficacy testing and monitoring during the ongoing operation of the plant.

To understand the requirements of testing and the formulation of a robust and successful sampling strategy, it is beneficial to understand the principles of disinfection and sterilisation in the most common commercial and currently available technologies in the UK.

## 2. COMMON TECHNOLOGY TYPES

### 2.1 Steam Disinfection / Sterilisation (Autoclave, Hydroclave, Rotoclave)

The basic principle of steam disinfection or sterilisation, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam disinfection/sterilisation:

- steam
- pressure
- temperature
- time

The ideal steam for disinfection/sterilisation is dry saturated steam with a dryness fraction ≥97%. Increasing pressure helps to achieve the high temperatures necessary to quickly kill microorganisms.

The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F).

The required disinfection/sterilisation temperature must be maintained for a minimal time to kill microorganisms.

### 2.2 Other Thermal Sterilisation Technologies (auger, microwave, infrared, friction)

Other thermal technologies rely on heating the waste and using its naturally entrained moisture to generate steam in a non-pressurised system to enable efficient thermal transfer to kill micro-organisms, these systems will run at lower (atmospheric pressure) steam in combination with heated jackets, augers, microwaves, or friction to provide the thermal input.

### 2.3 Chemical technologies (chemical disinfectants)

There are various non thermal sterilisation processes commercially available and used within the healthcare sector. For all the chemical technologies, sterilisation is enacted by the physical contact of the micro-organism with the chemical sterilant. These processes can inactivate a broad range of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores.

## 3. PRINCIPLES OF MICROBIOLOGICAL TREATMENT EFFICACY TESTING

### 3.1 Overview

The purpose of microbiological treatment efficacy testing is to demonstrate that the treatment process can reliably meet a pre-determined standard for disinfection or sterilisation, during commissioning and then consistently throughout the operational life of the plant.

The required standards that must be met are those defined by the International Society on Analytical Analysis of Treatment Technologies (IStAATT) for level III or IV treatment.

Biological indicators, or spore tests, are the most accepted means of monitoring sterilisation or disinfection because they assess the treatment process directly by killing known and certified populations of highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species).

IStAATT Level III and IV are validated using either *Geobacillus stearothermophilus* or *Bacillus atrophaeus* (see Table 1) in a worst-case scenario challenge load (Maximum kg).

### 3.2 Pass Criteria:

**Level III:** must achieve at least a Log 4.0 inactivation of the thermo-resistant spore population. Achieving level III inactivation means that the criteria for disinfection have been met. This is the basic minimum standard that must be met for all clinical waste disinfection treatment processes in the UK.

**Level IV:** must achieve at least a Log 6.0 inactivation of the thermo-resistant spore population. Achieving level IV inactivation means that the criteria for sterilisation have been met. This higher standard may be required when higher risk infectious substances are to be treated (biohazardous substances including HG2, 3 and 4 pathogen cultures and class 2, 3 and 4 genetically modified microorganism cultures).

### 3.3 Selection of Competent Contractors

Operators must use competent contractors to undertake validation and testing work as follows:

- For validation testing (see section 4) a competent contractor must supervise the testing work onsite and the test samples must be processed by a competent laboratory.
- For routine efficacy testing (see section 6) the plant operator may undertake the testing work onsite, but the test samples must still be processed by a competent laboratory.

The regulatory guidance does not define exactly what qualifications and standards are required as there are no specific qualifications or standards (ISO, BS, EN or similar) that are directly applicable to clinical waste treatment validation and routine testing. The following text provides supplementary guidance to assist operators in choosing a competent contractor.

The regulator guidance states that '*Validation tests must be supervised by a suitably qualified, experienced and independent person*.'

**Suitably qualified** means that the contractor must hold recognised qualifications in a relevant subject. This may include qualifications as an Occupational Hygienist (such as Chartered Status) and relevant supporting academic qualifications (such as a degree in microbiology or similar). **Suitably experienced** will ideally mean that the contractor has experience of clinical waste treatment validations, however this may not always be possible for new entrants to the market. If an operator wishes to work with a new entrant to the market their experience in similar work (such as Occupational hygiene work related to biological hazards and exposure) should be assessed and consideration should be given to whether they can receive training and advice from persons with experience in clinical waste treatment validation.

**Independent** means that the persons undertaking the work are not employed by the permit holder / plant operator.

The regulator guidance states that '*An appropriately accredited laboratory must do the analysis. For the treatment of infectious wastes, tests must be supervised by an appropriately qualified microbiologist. Analysis must be carried out at an accredited microbiological laboratory.*'

**Appropriately accredited** will in most cases mean that the laboratory holds accreditation as either a medical laboratory (ISO 15189) or as a testing and calibration laboratory (ISO/IEC 17025). If the laboratory holds either of these accreditations and their certification includes microbiological testing, you can also be assured that the work will be supervised by an **appropriately qualified microbiologist**.

There are however no independently verifiable testing methods/standards for clinical waste treatment laboratory analysis, so consideration should be given to whether the laboratory has the relevant capabilities for the work irrespective of whether the laboratory is accredited. When selecting a new laboratory ask about their experience in culturing and enumeration of bacterial spores and ask to see a method statement for how they will conduct the work.

For both onsite and laboratory work, if you are not sure whether a new contractor meets the requirements, it is recommended that you seek advice from the relevant regulator and/or the HWMA before engaging the contractor and proceeding with any work.

### 3.4 Indicator Species by Technology Type

It should be noted that the testing and validation techniques are based upon the technologies most used within the healthcare and clinical sector for sterilisation of medical devices. As a result of this there are processes/technologies used in the healthcare waste sector that do not clearly fit into defined categories for selection of Biological indicators and for the selection of Chemical Integrator strips.

Table 1 below identifies the most common technologies and appropriate Biological Indicator species.

| Treatment Technology | Treatment type | Biological Indicator Species |
|---|---|---|
| Autoclave (Static and Rotary) | Thermal Pressurised Saturated Steam | *Geobacillus stearothermophilus* |
| Hydroclave | Thermal Saturated Steam | *Geobacillus stearothermophilus* |
| Hot Oil auger | Thermal oil screw processing system | *Bacillus atrophaeus* |
| Steam Auger | Thermal, Steam screw processing system at atmospheric pressure | *Bacillus atrophaeus* |
| Microwave | Thermal | *Bacillus atrophaeus* |
| Friction converter | Thermal | *Bacillus atrophaeus* |
| Chemical | Ethylene Oxide<br>Peracetic Acid | *Bacillus atrophaeus* |
| | Vaporised Hydrogen Peroxide | *Geobacillus stearothermophilus* |

**Table 1: Technology types and expectation of indicator species**

### 3.5 Selection of appropriate Biological Indicator species

Biological indicators (BIs) provide information on whether necessary conditions were met to kill a specified number of microorganisms (bacterial spores) for a given sterilisation process.

An appropriately certified test organism must be used for all Commissioning, Validation, and routine testing.

The two main manufacturers of appropriate Biological Indicators are:

- STERIS
- MESA Laboratories

In line with guidance, all biological Indicators must be selected to have a minimum D-Value of 1.8 minutes with D-Values established to ISO 11138 by the manufacturer.

The oldest and most recognized agent for inactivation of microorganisms is heat. D-values (time to reduce

the surviving population by 90% or 1.0 log10) allow a direct comparison of the heat resistance of microorganisms.

Because a D-value can be determined at various temperatures, a subscript is used to designate the exposure temperature (i.e., D-121C)

Heat-resistant non-spore-forming bacteria, yeasts, and fungi have such low D-121C values that they cannot be experimentally measured.

The Healthcare Waste Guidance states that:

For thermal treatment plant, the spores used must have a minimum certified D-value ≥1.8 minutes at either:

- 121°C wet heat* for GS
- 160°C dry heat for BA

*Use of the phrase "wet heat" has caused some confusion with regards to BI selection for use with processes that use steam and those that use saturated steam.

*Geobacillus stearothermophilus* has a D-Value which is determined for *Saturated steam* in a *pressurised system*, so it is the ideal Biological Indicator species for technologies which use pressure and saturated steam such as autoclaves and rotary autoclaves.

It should be noted that biological indicators with excessively high D-Values may pose an additional and unnecessary challenge to the process.

For example, in comparison to the minimum D-Value of 1.8-minutes, a D-Value of 3 minutes would add an additional 7 minutes at sterilisation conditions per treatment cycle, which could have a significant effect on treatment plant throughput and energy costs over a 4-year period between validation testing.

It should also be noted that if there is a significant change in D-Value from validation to routine efficacy testing, the plant operator may start seeing fails in the monthly test data purely as a function of the difference in D-Value rather than as a result of a reduction in plant performance**.**

### 3.6 Spore suspensions for Efficacy testing

At the time of publication, there are no commonly available biological spore suspensions with published D-Values in concentrations high enough to ensure sufficient spore loading for use in technologies where Biological Indicator Strips cannot be utilised.

There is one UK- based Biotech company that can produce *B.atrophaeus* suspensions in high titres with D-Value on a bespoke basis, but at present *G.stearothermophilus* is not available in high titre suspensions.

### 3.7 Parallel Monitoring

For thermal processes, spore tests must be supported by the parallel use of either:

- thermal indicator strips which indicate time and temperature of exposure.
- multi-point thermal data loggers co-located in the waste load.

<u>Chemical (thermal) Indicators</u>

Chemical indicators (CIs), as defined by the Association for the Advancement of Medical Instrumentation (AAMI) and International Organization for Standardization (ISO), are devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilisation process or used in a specific test of sterilisation equipment. For example, when placed inside packs, chemical indicators are used to confirm that sterilant achieved good penetration in the items being sterilised. Chemical indicators are used as internal and external indicators and as part of routine performance testing and load release. It is important to note that chemical indicators alone do not confirm that an item is sterile.

Indicator strips are available from a number of manufacturers, with the most common being:

- SterTec
- 3M STERIS
- Microspec TST
- Medisafe

According to ANSI/AAMI ST79 Comprehensive guide to steam sterilisation and sterility assurance in healthcare facilities, internal chemical indicators can be a Type 3, Type 4, Type 5, or Type 6. However, Types 5 and 6 are preferred as they provide the user with more information on critical sterilisation parameters.

As a minimum it is recommended that Type 4 indicators are used which show time and temperature, however type 5 or 6 strips can offer more visual data which can be beneficial to the plant owner and the consultants undertaking testing.

You must demonstrate that the time/temperature combination used must be indicative of the required microbial inactivation being achieved.

For example, ISO 11140-1 Type 5 chemical integrator strips with a permanent colour change if treatment conditions are achieved can be used. Type 5 Integrators are chemical indicators that react to the parameters of sterilisation and very closely mimic biological indicators without requiring incubation, if the permanent colour change is achieved then it is likely that the accompanying Biological Indicator will have been exposed to suitable treatment conditions to achieve full inactivation of the spores.

For example:

ISO: 11140-1:2005, Class 5

Colour change: Purple to Green, one way permanent.

Dimensions: 7.62cm x 1.905cm (3" x 0.75")

Check Mark Reaction Time:

- 5 minutes (+0/-45 sec.) at 121°C
- 1.5 minutes (+0/-15 sec.) at 132°C
- 1 minutes (+0/-10 sec.) at 134°C (+0/-2°C)

Long Bar Reaction Time:

- 12 minutes (+0/-2 min.) at 121°C
- 3.5 minutes (+0/-30 sec.) at 132°C

- 3 minutes (+0/-30 sec.) at 134°C

Short Bar Reaction Time:

- 35 minutes (+0/-5.5 min.) at 121°C
- 11 minutes (+0/100 sec.) at 132°C
- 10 minutes (+0/1.5 min.) at 134°C For example:

The Kill time for the population of MESA Geobacillus stearothermophilus Lot No: GST-521 is:

- 22.69 minutes at 121°C; and
- 0.60 minutes at 134°C

It can therefore be demonstrated that the Chemical Indicator reaction times match the biological inactivation of the chosen biological indicator, for both long bar reaction at 134°C and extended short bar reaction time for all parameters.

Use of Data loggers

There are various thermal data loggers available, however very few can survive a high temperature, high pressure environment. The most commonly used are those by Madgetech such as the HiTemp 140. The HiTemp140 can withstand temperatures ranging from -40°C to +140°C (-40°F to +284°F) but can measure extended temperatures up to 260°C (500°F) (probe dependent).

It should be noted that if the high temperature environment shield is used, the manufacturer recommends the use of the 5" probe to ensure accurate response times.

Issues with data loggers

- It is not cost effective to have a data logger with every biological indicator, so the technology lends itself more to use in a carrier with multiple BI attached.
- They are easily damaged in moving treatment systems, such as Rotoclaves and auger technologies
- If you lose the data or logger on a sample run, then that run may be considered void.
- Not suitable for microwave or chemical technologies.
- Collection of parallel data in non-thermal processes.

There are alternative indicator strips available for Ethylene Oxide or EO/HFCF mixtures and Hydrogen peroxide.

Where your technology does not fit within the normal treatment parameters you will need to identify what parallel indication method you will employ and demonstrate its suitability for prior agreement with the regulator, prior to commissioning and validation.

## 4. PLANT COMMISSIONING AND VALIDATION – INFECTIOUS WASTES

### 4.1 Overview

As part of the plant commissioning process, you must carry out performance validation tests to demonstrate that the treatment plant will render safe each of the waste types that your facility is permitted to treat. The plant must then be operated on an ongoing basis in accordance with the parameters defined during the validation test, as stated in the commissioning and validation report, and approved by the regulator. Routine efficacy tests (see section 6.1) must be undertaken with the plant operating in accordance with these parameters.

Within the regulator guidance document there is a requirement that the validation of plant performance for disinfection must be based on the following:

- the treatment of a worst-case challenge load – in terms of spore strip containment or insulation and presence of interfering or inhibiting substances or items
- the maximum quantity of waste that will be treated – that is the maximum batch size or throughput of the plant

The worst-case challenge load used must reflect the type and design of the treatment plant. This must take into account:

- the treatment technology type, i.e., thermal, chemical etc.
- If the waste is pre-shredded or not before treatment
- The efficient and safe collection of samples without increased risk to health or the environment.

The worst-case challenge load used must also reflect the real-world waste types and composition that will be treated. This must take into account:

- The moisture content and organic content of the waste
- The density of the waste
- The type of packaging used (for example will rigid plastic containers be present)
- Other physical or chemical factors that may impact treatment (for example does the waste contain individual heavy or dense items such as suction canisters)

Within the sampling protocol, full justification of the proposed sampling strategy and worst-case scenarios must be provided.

It should be noted that it is possible for sample loss to occur in validation testing and the testing protocol should justify the number of samples that will be used per load to ensure that the minimum sample requirements are achieved (see tables 2 and 3 for minimum sampling requirements).

For new plant validations, it is common to see higher sample numbers used until the sample losses (if any) are accounted for, which can then be adjusted accordingly for routine testing thereafter.

All recovered samples must be submitted for laboratory testing and the use of oversampling and selection of favourable samples is prohibited.

All reasonably practicable steps should be taken to ensure sample recovery.

Where samples cannot be recovered due to health and safety or environmental considerations (such as entering waste flock skips with potentially untreated, macerated wastes) it must be documented within the validation report.

If sample losses are significant, it is recommended that the sampling protocols are reviewed and revised where possible to ensure that statistical confidence is maintained in the final data.

### 4.2 Testing using Spore Strips

All Biological indicator strips and controls used must be of the same batch number.

All testing must be accompanied by the appropriate thermal loggers or indicator strips.

All validation testing must comprise a minimum of 3 distinct treatment cycles, retrieving the treated test packages before starting the next cycle. In total, you must hold a minimum of 6 untreated spore strips outside of the device to use as controls that you will compare with the treated strips.

Current guidance requires a minimum number of Biological Indicators to be recovered for each test cycle (defined as either a batch or the full throughput transit time in a continuous feed process). The minimum requirements are set out in table 2 below.

| Plant load (kg) or throughput (kg/hour) capacity | Recovered per cycle or collection | Total recovered (assuming 3 runs) | Retained as controls |
|---|---|---|---|
| 0 to 10 kg | 3 | 9 | 6 |
| 11 to 50 kg | 4 | 12 | 6 |
| 1 to 250 kg | 6 | 18 | 6 |
| 251 to 500 kg | 8 | 24 | 6 |
| 501 to 750 kg | 10 | 30 | 6 |
| Over 750 kg | 12 | 36 | 6 |

**Table 2: Minimum number of spore strips**

*Test Preparation: Spore strips – thermal treatment with pre-shredding or maceration*

Each spore strip is placed in a separate carrier designed to mimic normal conditions in the waste being treated. Examples used include net bags, tennis balls, socks, punctured plastic, or alloy containers. It is important that spore strips are distributed throughout the load (i.e., they aren't added to the waste in the same container or carrier). For example, where the waste remains in carts during treatment then the spore strips must be distributed equally within and between carts.

If metal containers are used, the spore strips must be insulated, for example using cotton wool or

equivalent, to prevent direct heat conduction. Each spore carrier containing a spore strip must be inserted loose into the bulk of the pre-shredded or macerated waste and distributed throughout the waste load.

You may only use fixed carriers or test ports for routine monitoring if you have demonstrated through additional parallel testing that there is no significant difference between the results from these and loose carriers.

*Test Preparation: Spore strips – thermal treatment without pre-shredding or maceration*

Spore strips are contained in the centre of filled, sealed items of varying size. These are representative of the toughest and most resistant items commonly found in healthcare waste, such as suction canisters and chest drains.

Repeated field testing has shown that the most robust type is Rocket Medical R54500 Blue single chamber chest drain, however other comparable products are available and may be used.

Each container should be filled with 1500 mL of water stabilised with a sodium polyacrylate gel to the manufacturers specification to ensure that the gel is the correct consistency, as errors in the mixture can significantly affect the thermal properties and performance of the gel in which the spores are entrained.

The test items should be placed in worst-case packaging, for example, sealed rigid bins or containers and bags, and distributed throughout the waste load.

**4.3 Testing Using Spore Suspensions**

Within the regulator guidance, examples are given for the use of spore suspensions within glass vials, however if the process can recover glass vials, then it falls into the earlier sampling strategies where spore strip integrity can be guaranteed and therefore spore strips should be used. Use of spore suspensions is therefore only recommended where spore strip integrity cannot be guaranteed and/or when spore strips cannot be retrieved from the process.

Use of spore suspensions within the waste where spore strip or vial integrity cannot be guaranteed requires suitable dosing of the waste with a Biological Indicator with a titre of not less than $1.0 \times 10^6$ spores per gram of waste processed.

You must test each plant over a minimum of 3 separate treatment cycles, taking representative samples from the treated material before starting the next cycle. The test must include a control run, where waste (treated clinical waste or a suitable surrogate waste material) is passed through the plant without activating the treatment process. You should add the same total quantity of spore suspension to each control and test run.

If the mass of the waste differs between each control and test run, you will need to correct the test data for each run (spores present per kg of sample) to account for this difference.

The minimum number of samples taken from the treated material is set out in Table 3 below.

| Plant load (kg) or throughput (kg/hr) capacity | Recovered per test run | Total recovered (assuming 3 runs) | Recovered per control run |
|---|---|---|---|
| **0 to 10 kg** | 3 | 9 | 3 |

| | | | |
|---|---|---|---|
| **11 to 50 kg** | 3 | 9 | 3 |
| **51 to 250 kg** | 4 | 12 | 4 |
| **251 to 500 kg** | 4 | 12 | 4 |
| **501 to 750 kg** | 5 | 15 | 5 |
| **Over 750 kg** | 5 | 15 | 5 |

**Table 3: Minimum number of samples to be retrieved – spore suspension method**

Each sample should be at least 0.1% of the waste load, with a minimum sample of 50 g for smaller units.

Samples must be preserved appropriately until received by the laboratory for testing and must be sent to the laboratory in a timely manner.

The entire test sample must be analysed, except for the control samples. You must achieve the required log reduction (the number of spores recovered from control samples compared with those recovered from the test samples) with 95% confidence.

**It should be noted that at the time of publication there are no commercially available spore suspensions in high enough titre with a D-Value that can be used for this testing within the UK.**

### 4.4 Interpretation and Reporting of Results

The site operator must ensure that their contractor is familiar with the requirements for interpreting, calculating, and reporting results for clinical waste treatment validations. The calculation and interpretation requirements are clearly set out in the regulator guidance; however, the following key points are reiterated as follows:

- Remember that the required number of control spore strips must also be analysed and enumerated to allow the calculation to be made.
- Remember that the test data used must include all the recovered spore samples.
- Remember that the statistical confidence calculation must be completed before the validation test outcome can be determined. It is not as simple as achieving a log4 reduction on each individual sample.

The contractor must ensure that the validation test report provides the following information:

- A clear statement as to whether the validation test has passed or failed the test criteria.
- Full details of the spore counts for each sample and control.
- Evidence of the materials used, and process followed for the test (spore and broth certification sheets, photos of the onsite spore preparation, sample launching and recovery.
- Information defining the operating parameters during the tests (dependent on treatment

technology, i.e., temperature, pressure, time, rotation speed, cycle time, spore retention time, cycle load (kgs), load per hour (kgs)) with supporting evidence (i.e., SCADA display images, cycle printouts, downloads etc.).

- Spore certification evidence.
- Certification for chemical (thermal) indicators, and data logger calibration certificates.

## 5. OTHER VALIDATION TESTS

Site operators should be aware that the clearly defined validation and routine efficacy testing requirements in the regulator guidance only apply to the treatment of infectious clinical waste (orange bag waste) without any chemical, pharmaceutical or anatomical content.

Should you wish to treat any wastes with chemical, pharmaceutical or anatomical content you will need to develop a justification and bespoke validation / testing protocol that includes the following:

- Information to explain how the process will treat the chemical, pharmaceutical or anatomical content to render it safe or destroy it.
- Information to explain why this is an appropriate treatment method.
- Information to explain how emissions to air / water / sewer / fugitive emissions will be controlled.
- A proposed testing protocol setting out the tests required to demonstrate that the treatment is effective, and the emissions controlled.

Note that the regulator will not approve the treatment of any clinical waste with chemical, pharmaceutical, or anatomical content until an appropriate justification and testing protocol has been submitted and approved by the regulator. The regulator may then allow treatment to proceed on a trial basis for the duration of the validation testing. Permission to treat such wastes on an ongoing basis will only be given when the regulator is satisfied that the testing demonstrates that the treatment is effective, and the emissions controlled.

Advice should be sought from the regulator before proceeding with any plans to treat waste with chemical, pharmaceutical or anatomical content, to ensure that the above requirements are followed and that any changes required to the environmental permit can be planned. In most circumstances the regulator will control such changes through the inclusion of pre-operational conditions in the permit which will require submission and approval of plans and test reports before any change to the wastes permitted for treatment can be made.

## 6. ROUTINE PLANT EFFICACY TESTING

### 6.1 Overview

The site operator must undertake regular routine efficacy testing to demonstrate that the plant continues to disinfect or sterilise to the required standard during the operational life of the plant, and in accordance with the plant parameters during commissioning and validation.

There must be a written test protocol for routine efficacy testing which is aligned with the commissioning and validation methodology. All Biological indicator strips and control must be of the same batch number and at least a D-Value of 1.8.

All testing must be accompanied by the appropriate thermal logger or indicator strips.

Care should be taken to ensure that the D-Value used for the Biological Indicators in the routine testing is

as close to that used in the Validation as is reasonably practicable.

All samples recovered must be sent to the laboratory for analysis.

The key requirements set out in the EA appropriate measures guidance (Routine plant efficacy testing section) are as follows.

- Testing frequency and the minimum number of spore strips / sub-samples used per test is specified in the EA appropriate measures guidance (measures 7 & 8).
- A minimum of 3 spore strips / sub-samples must be used for each individual test (measures 7 & 8).
- Qualitative or quantitative sampling is allowed (measures 5 & 6).
- 95% of individual spore strip / sub-sample tests must pass the required standard in each calendar year (measure 6).
- Operations must cease if at any point the number of failures exceeds the annual 5% allowance.

This guidance seeks to provide a practical interpretation of these requirements for operators to implement consistently in the field. The following recommendations are made.

**6.2 Test Frequency / Number of Samples**

The number of strips/samples used on each individual test is 3.

As noted in the appropriate measures guidance the percentage success criteria allow for both potential contamination and the uncertainty of microbial data, however if only 3 strips are used this allowance is marginal to non-existent for smaller treatment plants. Operators may wish to consider defining a test schedule using a greater number of test samples.

The guidance does not specify a test frequency for plants with a capacity exceeding 1000 kg per hour or batch. It is therefore recommended that the frequency remains at monthly for such plants.

The planned testing schedule (frequency, samples per test, method) must be defined at the start of the calendar year.

In addition to the strips/samples that are treated, on each test a minimum of 1 untreated control sample must be retained and sent to the laboratory for analysis.

**6.3 Qualitative versus Quantitative Samples**

It is recommended that quantitative sampling is used as best practice. This avoids the risk of needing to transition from one testing method to another in the event of qualitative test failures and ensures that the most robust method is always used. Quantitative testing also allows the operator to see changes in treatment performance (i.e., variability in kill rate beyond a simple PASS / FAIL).

Control data must be provided with the laboratory analysis and used in the determination of log inactivation of the chosen Biological indicator.

If the theoretical population of the spore suspension is $\geq 1.0 \times 10^6$ and there is a population recovery of $<1.0 \times 10^6$ on the control, a $1.0 \times 10^6$ spore inactivation cannot be claimed even if there is no growth on the test samples.

### 6.4 Interpreting the 95% pass requirement

If at any point during the calendar year the number of failures exceeds the annual 5%, operations must be ceased pending identification of the cause and recommissioning. This must be interpreted as exceeding the 5% failure rate as a proportion of the total of the tests scheduled for the year or as a proportion of the tests completed on a rolling 12-month basis, and not as exceeding the 5% failure rate for tests completed in the calendar year to date. The latter interpretation would arbitrarily increase the risk of plant shut down in the earlier part of the year on the basis of a single anomalous result.

The following tables set out the number of failures that must be recorded for each size of plant before the 95% pass rate cannot be met for a test programme using either 3 or 5 samples per test.

| Plant Capacity | Tests per annum | Samples per Test | Total samples per annum | Min. tests passed for 95% | Max. tests failed for 95% | 95% unachievable tests failed |
|---|---|---|---|---|---|---|
| 0 to 50 kg | 4 | 3 | 12 | 12 | 0 | 0 |
| 51 to 500 kg | 6 | 3 | 18 | 18 | 0 | 0 |
| >501 kg | 12 | 3 | 36 | 35 | 1 | 2 |

**Table 4: 95% pass criteria – 3 samples per test**

| Plant Capacity | Tests per annum | Samples per Test | Total samples per annum | Min. tests passed for 95% | Max. tests failed for 95% | 95% unachievable tests failed |
|---|---|---|---|---|---|---|
| 0 to 50 kg | 4 | 5 | 20 | 19 | 1 | 2 |
| 51 to 500 kg | 6 | 5 | 30 | 29 | 1 | 2 |
| >501 kg | 12 | 5 | 60 | 57 | 3 | 4 |

**Table 5: 95% pass criteria – 5 samples per test**

### 6.5 Out of Date Biological Indicators

Due to the UK specific D-Value requirements for Biological Indicators, there have been instances in the past where no commercially produced spore strips were available when existing spore supplies were approaching the use by date.

In these rare instances it is recommended the Regulator is contacted to seek confirmation that testing can continue with the provision of additional control strips being submitted to the Laboratory.

Laboratory research has shown that when Biological Indicators near or exceed their use by date, the

population of spores slowly starts to reduce, but with additional control data to demonstrate that recovery is still above 1.0 x $10^6$ log of the original population, then in emergency situations, these strips could still be used in parallel with chemical integrator strips, or data loggers to determine routine efficacy.

## 7. MANAGING TEST FAILURES

The approach to managing test failures set out in the following table is recommended.*

| Efficacy Test Result | Action |
|---|---|
| 1 or more spore strip failure in any one test.<br><br>Spore suspension failure in one test.<br><br>Result does not render the 95% annualised pass rate unachievable | • The Regulator must be informed immediately of the test failure.<br>• The processing of waste may continue, unless otherwise instructed by the regulator, provided that thermal indicator strips or data logger, and plant parametric data all demonstrate that minimum treatment time and temperature were achieved.<br>• An investigation must be undertaken to determine the cause of the failure. The investigation must consider all potential factors that may have contributed to the failure.<br>• The regulator must be informed of the outcome of the investigation as soon as is reasonably practicable, including the identified causes of the failure and any corrective actions taken. |
| Total failures in the year sufficient to render the 95% annualised pass rate unachievable | • Immediately cease the processing of waste;<br>• The Regulator must be informed immediately of both the test failure and the total number of failures recorded since the start of the calendar year;<br>• Process residues currently on site must be held on site until direction is received from the regulator as to whether the residues must be reprocessed, incinerated, or may be sent for recovery or to landfill;<br>• An investigation must be undertaken to determine the cause of the failure. The investigation must consider all potential factors that may have contributed to the failure as well as any historical trends in the performance of the process;<br>• The regulator must be informed of the outcome of the investigation, including the identified causes of the failure and any corrective actions taken.<br>• The processing of waste may only recommence with the approval of the regulator. The understanding from the HWMA is that the regulator may take the following approach:<br>  ○ Approval to recommence processing will be given promptly provided that appropriate evidence of investigation, root cause |

| | |
|---|---|
| | analysis and corrective action planning has been provided by the operator.<br>○ It must be recognised that it in many cases it will be necessary to operate the plant to conclude the investigation, complete the corrective actions and undertake further testing.<br>○ The regulator and operator will agree appropriate timescales for completing any further external testing or if necessary, a full revalidation exercise. Given that lead times to schedule a full validation may be significant, allowance to operate in the interim with increased routine testing frequency may be given.<br>• The exact requirement for increased routine testing will be agreed on a case-by-case basis, but daily internal efficacy tests and weekly external lab cultured efficacy testing is recommended.<br>• Once the processing of waste recommences, process residues must be held on site until daily efficacy tests for that day show that the required level of inactivation has been achieved and this has been agreed by the regulator. Where the required level of inactivation has not been achieved the residues must be reprocessed or incinerated.<br>• Within the first seven days after recommencing operations an additional external test must be conducted.<br>Note: Internal daily efficacy tests and extra external tests conducted outside the normal schedule must not be included when determining the overall efficacy of the process at the end of each year. |

**Table 6: Test Failure Responses***

**Please note that the approach set out in table 7 differs slightly from the current requirements in Scotland, as defined in the SEPA guidance. Operators in Scotland should refer to the SEPA guidance and seek advice from their site officer (https://www.sepa.org.uk/media/w0qdaa1l/guidance-for-the-storage-and-treatment-of-healthcare-waste.pdf).*

It should be noted that the pass rate criteria and response to failure set out in the section above are appropriate to a plant during normal operations outside the first six months post-commissioning.

If the plant fails to pass any routine efficacy tests during the first six months of operation, then this guidance remains relevant in general however it may be appropriate to move directly to the final step of arranging a full recommissioning and validation exercise for the plant. In this scenario advice should always be sought from the regulatory officer for the facility.

## 8. MONITORING OF EMISSIONS TO AIR AND SEWER

### 8.1 Overview

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.

**Spore suspensions-**

High titre *B.atrophaeus* spore suspensions must be produced to ensure that testing is carried out to the maximum weight/throughput the plant can achieve.

If testing and suspensions are made to a lighter process mass, then that is likely to be set as the maximum allowable process load for that validation 4-year cycle.

**For example**: if a static Autoclave can process a maximum of 2000 kg per cycle but spore suspensions are made up to 1500 kg as that is a more typical load in use, then the bio-aerosol emission testing is only valid for loads up to 1500 kg.

If a 2000 kg spore suspension is made for testing, then the plant is receiving a worst-case challenge spore load even if the process weight is itself lighter on the day of testing.

It is therefore imperative that the either the maximum process weight or the highest load that a site operator wants to process to, are discussed before the sampling protocols are written and submitted to the Regulator prior to testing.

Due to the fermentation and growth process the exact spore count of new suspension is not known until post manufacturing, therefore you need to be able to demonstrate the titre of the spore suspension and volume required to ensure the correct spore density for the mass of waste to be processed.

**For example:**

A *B.atrophaeus* spore suspension is manufactured and produces $5.0 \times 10^9$ spores per mL A static Autoclave processes a maximum of 2000 kg per treatment cycle.

To ensure a $1.0 \times 10^6$ per gram spore density in a 2000 kg load, a total spore loading of $2.0 \times 10^{12}$ is required.

Therefore, based on $5.0 \times 10^9$/mL suspension a total of 400 mL is required.

**8.2 Sampling**

The purpose of the bio-aerosol testing is to determine the integrity of the waste handling process from the point of the bin/bag coming into the building though to post treatment waste compaction, with specific focus on:

- Hand loading of bins (if applicable)
- Bin washing
- bin tip operations
- maceration of wastes (particularly for pre-shred operations) with samples taken from the

shredder bin interface and post HEPA filter for discharge to atmosphere

- loading for treatment
- during the treatment cycle itself
- any pre vac stages and venting to atmosphere, condensing or other discharges to air and water
- unloading, post treatment waste handling and compaction.

Your sampling protocol should identify all areas of active sampling and the location of all settle plates for prior agreement with the regulator before the commencement of sampling.

**8.3 Growth media**

As part of the sampling strategy the choice of growth medium should be stated, and justification given for its selection and use. Where possible this should be accompanied by data from the supplier to demonstrate that the media is suitable.

In most instances Tryptone Soya Agar (TSA), called Soybean-Casein Digest Agar Medium by the United States Pharmacopeia is a good general-purpose non-selective growth medium that supports the growth of most Gram -negative and non-fastidious Gram-positive bacteria as well as many yeasts and moulds.

**8.4 Active bio-aerosol sampling**

Active airborne sampling for the *B.atrophaeus* tracer suspension spores should ideally be undertaken using a high-volume impaction sampler such as the Casella Slit sampler or equivalent.

Lower sample volume samplers using smaller diameter agar plates are available, but the sampling regime need to be adapted to ensure that sufficient air volume is collected onto multiple samples to ensure that any short duration high spore load emission is collected accurately.

Smaller volume air samplers may also struggle to obtain a representative sample from within discharge vents and process emissions to atmosphere due to only providing a low negative pressure suction, which may under sample in high flow transport velocities.

**8.5 Settle plate sampling**

Settle plates are used at selected positions around the plant including at entry/exit points to the building. The guidance calls for using a grid like pattern and this should be adhered to with the understanding that within areas of high traffic and bin movement it may not be reasonably practicable or safe to sample in these areas, without disrupting the activity of the plant (in which case the sampling is no longer representative of standard operating conditions).

The sampling program should include 6 samples per location (1 per hour) with an exposure duration chosen to collect sufficient sample without the risk of common environmental microflora colonising the sample media and causing overgrowth and loss of the sample.

Although *B.atrophaeus* has a distinct colour and morphology to assist in laboratory identification, if the growth media is heavily contaminated with other environmental organisms, then accurate identification and colony counts is not possible.

The 6-interval settle plate sampling will take place over a 6-hour period, to include the introduction of the test organism through to the discharge and compaction of treated waste and standard processing

thereafter to allow for any airborne spores to settle.

As a minimum, sampling must encompass at least 2 hours of processing after the spore suspensions have been processed to ensure that airborne spores have ample time to disperse around the plant and be detected.

### 8.6 External sampling

Sampling via settle plate or active sampler external to the process building is not recommended due to the potential issues with contamination with environmental micro-organisms. It should also be noted that weather conditions will also have a significant and detrimental effect on the sampling media and sample validity.

With a robust sampling strategy in place including all discharges to atmosphere, there should be no justifiable requirement for external or boundary sampling.

## 9. NEW TECHNOLOGIES

If you are looking to bring new technologies into the UK marketplace, it must be understood that test data generated from other countries is not accepted as to be comparable with the requirements listed in the regulator guidance.

Likewise, type approval is not applicable for a technology and each plant/technology is validated based upon the specific site location, permit requirements and associated plant and infrastructure.

It is therefore recommended that before new technologies/plants are imported/purchased or designed, a full review of the testing methodologies is undertaken, including how the new technology will fit into the existing test requirements stated in the relevant regulator's guidance.

Where the new technology does not clearly fit into the predefined test requirements, then suitable and sufficient test protocols must be established and submitted to the regulator for approval as part of the site-specific permit application, this should also include the laboratories analytical methods and capabilities.

It may also be prudent to consider proof of concept testing to demonstrate that the new testing regime is robust and meets the statistical certainties and recoveries required by the regulator.

## 10. CONFOUNDING FACTORS

There are a number of factors which may impact upon both the commissioning validation and the routine efficacy testing for alternative technology plants.

A significant change in waste composition may change the way in which the thermal treatment, heat penetration, steam penetration or retention of thermal mass affects the treatment efficacy of the process itself.

This was seen during the Covid 19 pandemic with a significant increase in PPE within the waste loads increasing the volume of waste and reducing the mass.

The most serious effects observed were:

- the reduction in waste with a pulpable mass that could retain the heat and steam in a thermal process

- increased thermal inputs needed for augers due to increase in condensate emission and temperature loss
- increase in thermal barrier forming on the thermal flights in augers due to melted plastics and rubbers
- significant compaction of wastes containing a high rubber and plastic mass in static autoclaves forming a barrier to steam and thermal penetration into carts reducing the treatment efficacy in the centre and at the bottom of waste loads

These current issues have been addressed with process engineering changes where they have arisen, but plant operators, regulators and companies involved in testing need to be aware of upcoming challenges to ensure that variations in waste composition do not adversely affect plant performance or environmental emission.

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