Appendix 9

Microbiological Efficacy Testing Report

WELL
ENVIRONMENTAL
SOLUTIONS

Independent consultants
to the health care industry

MICROBIOLOGICAL EFFICACY TESTING

STI MODEL 2000
CLINICAL WASTE TREATMENT PROCESS

&

REQUIREMENT FOR
ANNUAL PROCESS EFFICACY TESTING

Prepared for Sterile Technologies Ireland Ltd.

AUGUST 2003

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Microbiological Efficacy Testing of the STI Model 2000 clinical waste treatment process and the requirement for Annual Process Efficacy Testing

A Report prepared for
Sterile Technologies Ireland Ltd.

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EXECUTIVE SUMMARY

The STI model 2000 process has been repeatedly proven to achieve the required level of microbial inactivation both in commissioning tests, further microbiological testing to demonstrate inactivation in hypodermic needles, and ongoing weekly spore testing by two independent laboratories. Daily spore tests are also carried out by STI.

The results of these tests have proven conclusively that the STI Model 2000 process can achieve the required level of inactivation (STAATT level III, or 4 $\log_{10}$ reduction in *B subtilis* spores) and can reproducibly achieve STAATT level IV inactivation, which is 100 times greater than required.

Microbiological studies have demonstrated the operating parameters at which the process can reproducibly achieve the required level of inactivation, which is acknowledged to provide a margin of safety, and has shown which operating parameters fail to achieve the required level of inactivation.

Latest guidelines from the USA recommend that, once a technology has been successfully microbiologically commissioned, further biological indicator testing is not required.

In the UK, current guidelines recommend a 6 month period following microbiological commissioning where weekly spore tests are performed, but following successful conclusion of this, this requirements may be relaxed.

I would support the requirement for ongoing spore testing rather than relying entirely on parametric monitoring.

I do not believe that a requirement for 'process efficacy testing' to be repeated annually is supported by the published guidelines or recommendations in the field of clinical waste treatment.

INTRODUCTION

This report has been produced for Sterile Technologies Ireland ltd.

In line with international licensing requirements and licensing requirements in England[1], Wales and Scotland[2,3], new technologies for the treatment of clinical waste must undergo microbiological validation testing to prove the efficacy of the system[4].

These tests are best carried out under the auspices of an experienced microbiologist and must demonstrate efficacy to internationally agreed criteria. [4,5,6]

The STI plant in Dublin has had these initial tests performed by competent laboratories, and have been proven to be capable of achieving the required level of microbial inactivation.[8]

STI have been asked to provide microbial validation testing, referred to as 'process efficacy testing' on a yearly basis. This is microbiological testing similar to repeating the original microbial commissioning and validation testing.

STI have questioned the need for this testing and have asked me to prepare this report to inform the decision making process in this respect.

BACKGROUND

With the emergence of a number of new, alternative technologies for the treatment of clinical waste in the United States, there developed a need to regulate these technologies and to ensure that they actually made the waste safe by inactivating pathogenic micro-organisms within it. The evolution of microbial efficacy testing was thus initially driven by state agencies responsible for environmental or healthcare matters as a response to US federal government legislation.[5,9]

The development and use of these alternative technologies raised concerns regarding the potential for occupational health and safety problems, as well as environmental damage caused by their operation at healthcare facilities and commercial treatment centres.[9]

In 1994, a group of experts in America (STAATT) including representatives from environmental and public health agencies of approximately 15 states published a report outlining some of the important factors that must be considered before a new clinical waste treatment process can be licensed.[4]

This report defined four levels of microbial inactivation (I to IV) as follows:

Table 1

Level I	Inactivation of vegetative bacteria, fungi and lipophilic viruses at a 6 $\log_{10}$ reduction or greater
Level II	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater
Level III	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater; and inactivation of *B stearothermophilus* or *B subtilis* spores at 4 $\log_{10}$ reduction or greater
Level IV	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites, mycobacteria and of *B stearothermophilus* spores at 6 $\log_{10}$ reduction or greater

Adoption of level III criteria as the minimum required for clinical waste treatment processes was recommended by STAATT.[4]

STAATT also emphasised that in order to establish proper testing protocols that incorporate the recommended criteria and meet any applicable recognised testing standards, an independent laboratory should be used, which is experienced in microbiological testing techniques and is familiar with the required sampling and testing protocols (ref 4 p21 para 2).

Since 1994, many other regulatory bodies have followed the guidance of STAATT and have adopted the recommendations therein (ref 9 p 3). Thus, the microbiological efficacy testing protocols have been accepted and promoted as correct by the

Environment Agency (EA) in England and Wales[1], NHS Estates (HTM 2075)[6], the Scottish Environmental Protection Agency (SEPA) and the NHS in Scotland[2].

RECENT DEVELOPMENTS

Since the publication of the STAATT report in 1994, new technologies have been developed and new questions have been raised, therefore a second meeting of STAATT was held in 1998 and a second report was produced (STAATT II)[10] which included several modifications to the original report in the light of new knowledge and experience. This report has not been as widely published as the first one, and therefore not all of the new recommendations have, as yet, been incorporated into other guidelines.

Given the status of STAATT as the most widely accepted and authoritative source on alternative technologies for treating clinical waste, it is only a matter of time before these modified recommendations are incorporated in other guidelines.

REPRESENTATIVE BIOLOGICAL INDICATORS FOR MICROBIOLOGICAL EFFICACY TESTING

STAATT (1994) felt that spores of *B stearothermophilus* and *B subtilis* were the most chemically or thermally resistant biological indicators available (ref 4 p7 para 5). They were already used as indicators of medical product sterility because of this documented resistance (ref 4 p8 para 3).

The committee concluded therefore that the evidence available demonstrated that either *B stearothermophilus* and *B subtilis* spores could be used to represent vegetative bacterial, fungi and mycobacteria in evaluating both chemical and thermal treatment systems (ref 4 p7 para 2) and could therefore be used as representative biological indicators.

The demonstration that highly resistant spores from either of these species can be effectively destroyed by a treatment process ensures a margin of safety from the variables inherent in the treatment of clinical waste (ref 4 p9 para 1).

It was suggested that if a challenge of 1×10^4 Bacillus spores was treated, retrieved and cultured, then no growth would demonstrate a 4 $\log_{10}$ reduction (ref 4 p16 para 3), which would demonstrate achievement of STAATT level III .

Thus the Environment Agency in England and Wales also recommends STAATT level III criteria as the minimum required for clinical waste treatment,[1] and the NHS in Scotland also require the demonstration of a 4 $\log_{10}$ reduction in *B subtilis* spores.[2,3]

The Environment Agency suggested that the use of some of the pathogenic strains would not be required if spores of *B stearothermophilus* and *B subtilis* could be

obtained commercially in 'ready to use' form and proposed that inactivation of these spores is sufficient alone to demonstrate inactivation of the other organisms. (ref 1 p 64 para 2).

STAATT II agreed that level III inactivation criteria were still the most appropriate to demonstrate adequate treatment of clinical waste by new technologies.[10]

The STI plant in Dublin has been proven to meet STAATT level III inactivation criteria with B subtilis spores [7,8].

MICROBIOLOGICAL EFFICACY TESTING

In 1994, STAATT also differentiated the microbial testing protocols that should be used for validation of the efficacy of a new technology that had never been tested elsewhere (technology approval), and those required for the siting of a technology that has been operating elsewhere and has been validated elsewhere (site approval) on a new site.[4]

In this light, STAATT recommended that the rigor of the biological indicator testing required for the establishment of a treatment technology for site approval would be less than the testing required for technology approval (ref 4 p24 para 2).

MICROBIAL EFFICACY TESTING FOR TECHNOLOGY APPROVAL

In 1994, STAATT recommended that for technology approval, representatives of all the different microbial groups in table 1 should be tested and proven to be inactivated to the required level (Ref 4 p 13 para 2,4 and p22 para 10), although they noted that many of these organisms had the potential to be pathogenic.

However, STAATT II has modified this requirement to recommend that only Bacillus spores and Mycobacterium species are required for initial technology approval, as the use of additional biological indicators to demonstrate the efficacy of treatment systems provides no additional safeguards to public health and safety. [9,10]

The requirement to demonstrate 6 $\log_{10}$ inactivation of Mycobacteria and 4 $\log_{10}$ inactivation of Bacillus spores is still considered valid. [9,10]

The STI Model 2000 is in use in various parts of the world and has been extensively microbiologically validated in the United States. All these tests have proven that the system can reproducibly achieve STAATT level III inactivation or greater.[7,8,11,12]

These tests were conducted in compliance with the US Environmental Protection Agency regulations or guidance, with a range of vegetative bacteria, fungi, viruses, parasites, mycobacteria and bacterial spores and have met the required criteria (table 1) in each case.

Thus the STI plant at Dublin is not a new technology and does not require the rigor of new technology testing [1,4,10].

MICROBIAL EFFICACY TESTING FOR SITE APPROVAL

In contrast, it was recommended by STAATT in 1994, that for site approval, only the demonstration that bacterial spores could be inactivated to the required level, under typical waste load conditions, was necessary (ref 4 p24 para 2 and 4).

The Environment Agency in England and Wales also recommended this approach (ref 1 p 64 para 3)

STAATT II, in 1999 have made different recommendations however.

Stating that "once a technology has successfully met the initial efficacy test requirements, additional testing with biological indicators, either when first sited at a facility or as part of a regular quality control program, would not be required". [9,10]

"If a technology effectively demonstrated 4 and 6 $\log^{10}$ reductions of biological indicators within three different surrogate test loads under specific parameters, eg time, pressure, temperature, chemical concentration etc., then it follows that if these parameters are achieved that the system must be effectively treating waste. Consequently, only parametric monitoring would be required for validation and quality control testing". [9,10]

In addition, it was concluded that the testing of 'treated waste' for micro-organisms was not necessary or useful. [9,10]

The STI Dublin plant would therefore require only the demonstration of bacterial spore inactivation to STAATT level III for site approval under the old STAATT guidance, but under STAATT II recommendations would not need microbiological testing at all [4,10].

The STI Dublin plant has been proven to meet STAATT level III inactivation criteria with B subtilis spores. [7,8,]

PERIODIC USER VERIFICATION

In 1994, STAATT also recommended that user verification methodology is necessary to periodically verify to the equipment user and the state that the treatment unit is functioning properly, that proper operating procedures are used, and that performance standards are achieved (ref 4 p27 para 2).

This specifically required the equipment user to :

- Demonstrate on a periodic basis that the required resistant bacterial endospores (*B stearothermophilus* or *B subtilis*) are inactivated to level III criteria under standard operating procedures.
- Document the frequency of biological and parametric monitoring

- Document and record all biological indicator and critical parametric monitoring data

The Dublin STI plant carries out daily in-house *B subtilis* spore tests, the results of which are available for examination. The testing methods used conform to STAATT [4,10], Environment Agency in the UK[1] and World Health Organisation[13] requirements.

The frequency of these tests and the results are recorded, as are the parametric data.

The requirements of STAATT and the UK Environment Agency have been fulfilled during the operation of the STI Dublin plant [1,4,10].

STAATT (1994) also recommended that parametric monitoring could substitute or replace biological indicator inactivation monitoring if the following conditions were achieved (ref 4 p24 para 1):

- The process must have tamper-proof controls or automatic factory-set controllers
- Be integrated with the treatment unit to automatically shut down or no longer accept or expel waste if treatment conditions are not maintained at specified performance levels
- Be calibrated periodically as specified by the monitoring device's manufacturer
- Provide a tamper-proof recording of all the critical operating parameters

These conditions have been met by the STI plant in Dublin.

The Environment Agency in England and Wales also recommended this approach (ref 1 p 70 para 8)

However, the UK Environment Agency also recommended that, after commissioning, in addition to parametric monitoring, microbial inactivation be demonstrated not less than once weekly using bacterial spores. If this reliability of inactivation is demonstrated through 6 months of normal operations, this frequency may be reduced at the Agency's discretion (ref 1 p 71 para 6).

The STI Dublin plant has had daily microbial inactivation tests using spores of *Bacillus subtilis* performed both in-house and by an external independent laboratory. In-house tests have all proved the process capable of achieving STAATT level III or greater inactivation[7] since November 2000, and external laboratory testing has confirmed these as valid in 2002[7].

The STI Dublin plant has more than fulfilled this requirement for demonstration of microbial inactivation with daily spore tests. The results of these tests prove that the process can reproducibly inactivate clinical waste to the required level over a sustained period of time[7].

PARAMETRIC MONITORING

In 1994 STAATT recommended that proper correlation be made between parametric monitoring (such as steam pressures, temperatures, residence times, auger speeds etc) and biological indicator inactivation through documented studies linking microbial inactivation with the parameters being monitored (ref 4 p23 para 3 and 4)

The Environment Agency in England and Wales[1] and NHS Estates[6] have also recommended this approach.

In 1999, STAATT II produced further recommendations, where parametric tests alone were considered sufficient for ongoing monitoring following satisfactory microbiological commissioning, as long as the agreed parameters were maintained, and ongoing biological tests were not required.[10]

The STI plant at Dublin has had satisfactory microbiological commissioning and under STAATT II guidelines could be monitored on parametric controls alone.

DISCUSSION

The STI Model 2000 clinical waste treatment plants in Ireland have been extensively microbiologically tested and validated by independent laboratories and have been proven to reproducibly achieve STAATT level IV inactivation of *B subtilis* spores (ie 100 times the required level of inactivation) when the operating parameters were set correctly.

It is worthy of note that clinical waste contains fewer micro-organisms than domestic waste, and the same types of pathogenic micro-organisms may be present in both[1]. Some studies have shown that household waste contains on average 100 times more micro-organisms with pathogenic potential than hospital waste[14] therfore the achievement of STAATT level IV inactivation does provide a great margin of safety.

This has allowed experts in the field to conclude " we can deduce from our daily exposure to household waste and the decades of sanitary landfill burial, that the public health risks for the less microbiologically contaminated hospital waste are nominal"[14].

The American Centre for Disease Control has stated "there is no epidemiological evidence to suggest that current health waste disposal practices have caused disease in the community[15].

The STI model 2000 treats waste at greater than 80°C for around 1 hour on average at normal operational parameters. This is proven by direct measurement of temperature within the unit using a datalogger.

Evaluation of the scientific literature shows that with the exception of bacterial spores, all other micro-organisms are completely inactivated at temperatures of around 80°C[1].

Given the above, it is not logical to subject clinical waste treatment plants, which have been proven to consistently meet an extremely high level of microbial efficacy under established operating parameters, to repeated validation testing which adds nothing to the existing body of evidence.

The requirement for 'process efficacy testing' to be repeated annually is not supported by the guidelines or recommendations of any of the recognised authorities in the field of clinical waste treatment.

The independent microbiological efficacy tests that have already been carried out on the STI model 2000 process in the United States and in Ireland have conclusively proven that the system can consistently achieve the required treatment level with the stated operating parameters, and the ongoing microbiological monitoring has confirmed this over a much longer time and with much greater frequency than is recommended in any guidelines.

I have personally been involved in the microbiological efficacy testing of 19 separate clinical waste treatment processes, and no other regulatory body has required annual process efficacy testing.

It is my belief that annual process efficacy testing by an independent laboratory is not necessary in a system so well proven as the STI model 2000 and adds nothing to the body of information already in existence regarding the efficacy of the process.

If an annual revalidation is a real requirement, I would suggest that a better way would be for an independent consultant to audit the results obtained over the year by the daily in-house spore tests and any external microbiological testing performed.

In line with STAAT and UK Environment Agency guidelines, a permanent record of key operating parameters such as Auger speed, steam pressure and chamber temperature could be kept and this could be correlated with the results of spore tests.

This could also be audited annually and would provide much more valuable information on the efficacy of the system.

I would however, support the continuation of the on-going spore tests currently performed, as I have some concerns over the reliance on parametric controls alone. It is possible that the frequency of these tests might be reviewed in the light of the extremely good results achieved over the operating life of the plant so far.

CONCLUSION

The STI model 2000 process has been proven conclusively and repeatedly to achieve the required level of inactivation (STAATT level III, or 4 $\log_{10}$ reduction in *B subtilis* spores) and can reproducibly achieve STAATT level IV inactivation, which is 100 times greater than required.

As even STAATT level III is acknowledged as providing a margin of safety [1,4,5,6,9] the STI process must be regarded as capable of safely treating clinical waste under set operating conditions.

The STI model 2000 process is monitored parametrically and using spore tests on a daily basis, thus correlating the microbial efficacy of the system with parametric measurements, as recommended.

The STI process has been tested more than any other alternative clinical waste treatment system that I am aware of, and certainly more than regulatory bodies in the United States, England, Scotland and Wales require.

Given the accumulated microbiological test results available on the STI model 2000 system, I do not believe that annual process efficacy tests are warranted, and I can not see how they can add anything to the current level of knowledge.

I recommend that annual process efficacy tests be discontinued.

If an annual review of the systems performance is required by the regulatory body, I recommend that an independent consultant audit the test results obtained from in-house and independent spore testing over the year. This would provide a much more in-depth picture of overall efficacy than a simple repeat of commissioning tests.

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