VALIDATION AND MONITORING OF NON-BURN HEALTH CARE RISK WASTE TREATMENT FACILITIES IN GAUTENG

Linda Godfrey

Project Leader, CSIR Division of Water, Environment and Forestry Technology

Co-Authors:
Dave Baldwin, Environmental and Chemical Consultants
Martella du Preez, CSIR Environmentek
Pauline Coubrough, CSIR Environmentek

ABOUT THE SPEAKER

Linda Godfrey graduated from Rhodes University in 1991 with a BSc in geology and chemistry. Following an honours in geology in 1992, Linda went on to complete her MSc in geohydrology from Free State University in 1993. Linda has been working at the CSIR, within the Division of Water Environment and Forestry Technology since 1994. For the first 6 years of her career, Linda focussed on groundwater pollution projects, particularly the impacts of industry, waste disposal and mining on groundwater quality. Since 2000 Linda has played a fundamental role in the establishment of the CSIR's Centre for Integrated Waste Management, which brings specialists within the organisation together to provide innovative and integrated solutions to waste management problems within the country. The availability of state of the art analytical facilities within the CSIR provided the organisation with the opportunity to assist Evertrade Medical Waste in the validation of their Johannesburg and Cape Town facilities. It was this experience that allowed the CSIR to assist the Gauteng Department of Agriculture, Conservation, Environment and Land Affairs (GDACEL) and Environmental and Chemical Consultants, in the development of guidelines for the validation and monitoring of non-burn health care risk waste treatment facilities within the Province.

ABSTRACT

The recent introduction of non-burn, health care risk waste treatment technologies, such as ETD^{TM} autoclaving, microwaving and steam sterilisation into Gauteng Province, has required the development of both the standards and the monitoring procedures that will ensure that these treatment processes will provide an acceptable level of microbial inactivation and will continue to do so during the regular operation of a facility. The Gauteng Department of Agriculture, Conservation, Environment and Land Affairs (GDACEL) has decided to be guided by the standards and procedures developed by the State and Territorial Association of the USA (STAATT). GDACEL requires that all treatment technologies should attain Level III inactivation as a minimum, even those that treat and generate small amounts of waste. Level III inactivation requires a reduction of ≥ 6 Log_{10} of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria, and a ≥ 4 Log_{10} reduction of *Bacillus stearothermophilus* or *Bacillus subtilis* spores.

With no Provincial or National guidelines or procedures for validation testing and monitoring available in 2002, the microbiological validation of the EMW Operations facility in Johannesburg, the first non-burn treatment facility in South Africa, involved a steep learning process for the proponent, the microbiological testing laboratories and GDACEL.

Due to the limited time frames imposed on the validation process, it was found that certain ATCC cultures, as required by STAATT 1 were not available in South Africa and could not be imported during the available, limited time frame. In addition, no single laboratory in South Africa could provide all of the required analyses. Methods to ensure the introduction of microbial samples into the treatment process and the safe recovery of these samples, needed to be developed by the proponent and the laboratories. Close collaboration between EMW Operations, the laboratories and GDACEL, ensured that the most suitable organisms were used, within the given time frame, to provide successful validation results.

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INTRODUCTION

South Africa has traditionally utilised incineration as the technology for the treatment of the health care risk waste, infectious waste stream. However, recent developments, have led to the introduction of new technologies in Gauteng and other Provinces in South Africa. These technologies include Microwaving, Electro-thermal De-Activation (ETD) and Autoclaving; all of these technologies are non-burn technologies, i.e. they use various methods to heat the waste to a moderate temperature that, if maintained for sufficient time, should result in an acceptable level of sterilisation. Other technologies, such as Chemical Treatment, e.g. with chlorine or ozone, and irradiation, e.g. with UV or cobalt–60, are used in other countries and, in the future, may be introduced into South Africa. The Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste (DWAF, 1998) require that infectious waste be incinerated or otherwise sterilised prior to disposal of any ash or residues to a permitted hazardous, H:H or H:h landfill or possibly a general waste landfill. However, the definition of sterilisation and the acceptance and performance standards have never been properly defined. A number of I&APs have expressed the concern that these new technologies may give rise to environmental and occupational health and safety risks, unless quantitative standards are set and protocols are introduced to allow assessment of their efficacy.

In the absence of appropriate standards, the South African authorities have generally accepted those that have been developed by credible organisations such as the United Nations Environmental Programme, World Health Organisation and the United States Environmental Protection Agency.

This paper presents the approach adopted by the Gauteng Department of Agriculture, Conservation, Environment and Land Affairs (GDACEL) in developing Guidelines for the validation and monitoring of non-burn, health care risk waste treatment facilities in Gauteng.

STERILIZATION VERSUS DISINFECTION

It is important distinguish early on, the difference between *sterilisation* and *disinfection* when assessing the microbial inactivation of treatment facilities. As mentioned in the Minimum Requirements (DWAF, 1998), infectious waste must be incinerated or otherwise sterilised prior to disposal. Non-burn treatment facilities are not typically required to disinfect health care risk waste. The Centre for Disease Control in Atlanta distinguish between sterilisation and disinfection, as follows (Garner & Favero, 1986).

- *Sterilisation* is a process that reduces the number of microorganisms by a factor of one million (10^6 or more than 99.9999% are killed), i.e. a Level III microbial inactivation.
- *Low Level Disinfection* is where most bacteria, some viruses and some fungi are killed, but the complete absence of resistant microorganisms such as tubercle bacilli or bacterial spores cannot be relied on.
- *Intermediate Level Disinfection* is where Myocardium tuberculosis, most viruses and fungi are killed, but not necessarily bacterial spores.
- *High-level Disinfection* is when all microorganisms with the exception of small numbers of bacterial spores are killed.

Organisms may be ranked according to their resistance to sterilisation and disinfection, as indicated in Table 1 (Favero & Bond). As indicated in Table 1, bacterial spores such as *Bacillus stearothermophilus* or *Bacillus subtilis*, are seen to be the most resistant organisms to treatment.

APPROACHES AND STANDARDS

State and Territorial Association on Alternative Treatment Technologies

The State and Territorial Association on Alternative Treatment Technologies (STAATT) met between 1992 and 1994 to develop a guideline document for environmental and public health agencies in America, outlining the technical and administrative procedures for the review and approval of all treatment systems, particularly the new alternative technologies. In 1994, STAATT released the Technical Assistance Manual

State Regulatory Oversight of Medical Waste Treatment Technologies (STAATT, 1994), referred to as STAATT 1. STAATT 1 recommended a Level III microbial inactivation of medical waste by treatment technologies, i.e. inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at 6 Log_{10} reduction; and inactivation of *B. stearothermophilus* or *B. subtilis* spores at 4 Log_{10} reduction. The inactivation must be verified by testing one organism from each of the following groups:

Vegetative Bacteria:
- *Staphylococcus aureus* (ATCC 6538)
- *Pseudomonas aeruginosa* (ATCC 15442)

Fungi:
- *Candida albicans* (ATCC 18804)
- *Penicillum chrysogenum* (ATCC 24791)
- *Aspergillus niger*

Viruses:
- *MS-2 Bacteriophage* (ATCC 15597 – B1)

Parasites:
- *Cryptosporidium* spp. oocysts
- *Giardia* spp. cysts

Mycobacteria:
- *Mycobacterium terrae*
- *Mycobacterium phlei*
- *Mycobacterium bovis* (BCG) (ATCC 35743)

Spores:
- *Bacillus stearothermophilus* (ATCC 7953) [1]
- *Bacillus subtilis* (ATCC 19659)

In 1998, after further research, STAATT released their second report (STAATT 2), in which it was shown that "the use of additional biological indicators to demonstrate the efficiency of treatment systems provides no additional safeguards to public health and safety". The list of test organisms was reduced to Mycobacteria and *Bacillus* spores only, i.e. a reduction in *mycobacteria* of ≥6 Log_{10} and of *B. stearothermophilus* or *B. subtilis* spores of ≥4 Log_{10} (STAATT, 1998).

Table 1. Microbial resistance to treatment in descending order.

BACTERIAL SPORES
(e.g. *Bacillus Subtilis*, *Clostridium sporogenes*)
↓
MYCOBACTERIA
(e.g. *Mycobacterium tuberculosis* var. bovis)
↓
NON-LIPID OR SMALL VIRUSES
(e.g. *Poliovirus*, *Coxsackie virus*, *Rhinovirus*)
↓
FUNGI
(e.g. *Trichophyton spp*, *Crytococcus spp*, *Candida spp*)
↓
VEGETATIVE BACTERIA
(e.g. *Pseudomonas Aeruginosa*, *Staphylococcus Aureus*, *Salmonella spp*)
↓
LIPID OR MEDIUM SIZED VIRUSES
(e.g. Herpes Simplex Virus, *Cytomegalovirus*, Respiratory syncytical virus, Hepatitis B Virus, Human Immunodeficiency Virus)

US State Departments

The approach to evaluate the efficacy of alternative treatment technologies in US States varies. Some of the States have adopted the STAATT1 testing requirements, while others have adopted relaxed STAATT1 or 2 requirements, placing more of an emphasis on parametric monitoring. In most instances, even where

[1] Strain derived from ATCC # 7953 has been reclassified and is now called *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). The reclassification is a name change only. The strain and its use remain the same. For additional information, visit www.ravenlabs.com/taxonomy.pdf.

STAATT1 is applied, parasites are excluded from the testing, due to the difficulties associated with the organism and the test methods.

South African Requirements

South Africa has as yet, no Guideline Document for the validation of non-burn health care risk waste treatment facilities. Provincial Departments are however, in the process of drafting Guidelines and Standards for Testing. This is discussed further in this paper.

CASE STUDY 1

Evertrade Medical Waste, which makes use of Electro Thermal Deactivation (ETD^{TM}), submitted a request for approval of their non-burn health care risk waste treatment plant in 2002. Being the first non-burn health care risk waste treatment facility in South Africa, provided a number of challenges for the authorities, in particular the requirement for microbiological validation and efficacy testing. With no South African guidelines to fall back on, GDACEL adopted the conservative, STAATT1 requirements, developed in 1994.

The following minimum requirements for Performance Testing were requested by GDACEL.

a) A period of one calendar month is allowed for testing of the Electro Thermal Deactivation unit.
b) The following deactivation requirements must be met:
   (i) As a minimum, Level III microbial inactivation must be demonstrated by the technology, i.e. inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at ≥ 6 Log_{10} reduction; and inactivation of *B. stearothermophilus* or *B. subtilis* spores at ≥ 4 Log10 reduction.
   (ii) GDACEL reserves the right to require Level IV microbial inactivation, if wastes being treated are particularly virulent, i.e. from laboratories that handle or maintain stocks of disease causing agents.
   (iii) One or more representative biological indicators from each microbial group, as listed by STAAT1, must be used by the facility to demonstrate that the microbial inactivation requirements as required above can be met.
   (iv) The testing programme was to be carried out weekly for a one month period, i.e. at least 4 times, on “normal” infectious waste.

In addition, a number of monitoring and test requirements were stipulated with regards to the standard procedures to be used, the types of waste to be used in testing and the frequency of testing.

Test Procedure

Following discussions between EMW Operations, GDACEL and the laboratories, liquid microbial samples were exposed to the ETD^{TM} treatment process to determine the ability of the process to inactivate the different microbes. Microbes tested included vegetative bacteria (*staphylococcus*), a yeast (*Candida albicans*), bacteriophages (MS-2 and V1) representing viruses, an endoparasite (*Cryptosporidium* parvum), *mycobacteria* and a spore former (*Bacillus subtilis*). Plaques produced by the MS-2 bacteriophage are often difficult to observe and can produce false negative results. Therefore, at the request of the laboratory, the V1 bacteriophage, which is easier to observe, was tested for in addition to the MS-2, to allow for verification of results.

Liquid samples, 12 vials per run, of each microbe were tested in a minimum of four replicate runs. In order to ensure the required Level III microbial inactivation, MS2 and V1 bacteriophage samples contained 10^6 plaque forming units (PFU), *Candida albicans* samples contained 10^6 colony forming units (CFU) and *Bacillus subtilis*, AllKil^{TM} samples contained 10^4 colony forming units (CFU) per ml. During application of the treatment process, four vials of each organism, were placed at each of three locations, approximately one quarter of the way from each end of the middle of the ETD^{TM} tube, to provide accurate treatment simulations. Four vials at each location were used to allow for vial breakages which were expected, due to the forces generated by the hydraulic waste infeed to the ETD^{TM} treatment tube. Matched control samples were handled identically except that they were not placed into the treatment system. The test vials were exposed to the treatment process for a period of 10 min. After an appropriate holding period, the control and treated samples were placed on ice and transported to CSIR, Environmentek laboratories for quantitative enumeration of viable organisms.

Results

Samples were submitted to the CSIR, Environmentek and National Health Laboratories for testing. Results presented here are for those tests conducted by the CSIR, namely *Bacillus subtilis*, MS-2 bacteriophage, *Candida albicans* and *Cryptosporidium*. Tests for vegetative bacteria and mycobacteria were conducted by the National Health Laboratory.

Results obtained for all test organisms, indicated that the Stericycle ETD™ treatment process employed by EMW Operations, met the Level III requirements set by GDACEL of a 6 Log_{10} inactivation for vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria, and a 4 Log_{10} reduction for spores. The results are presented graphically in Figure 1.

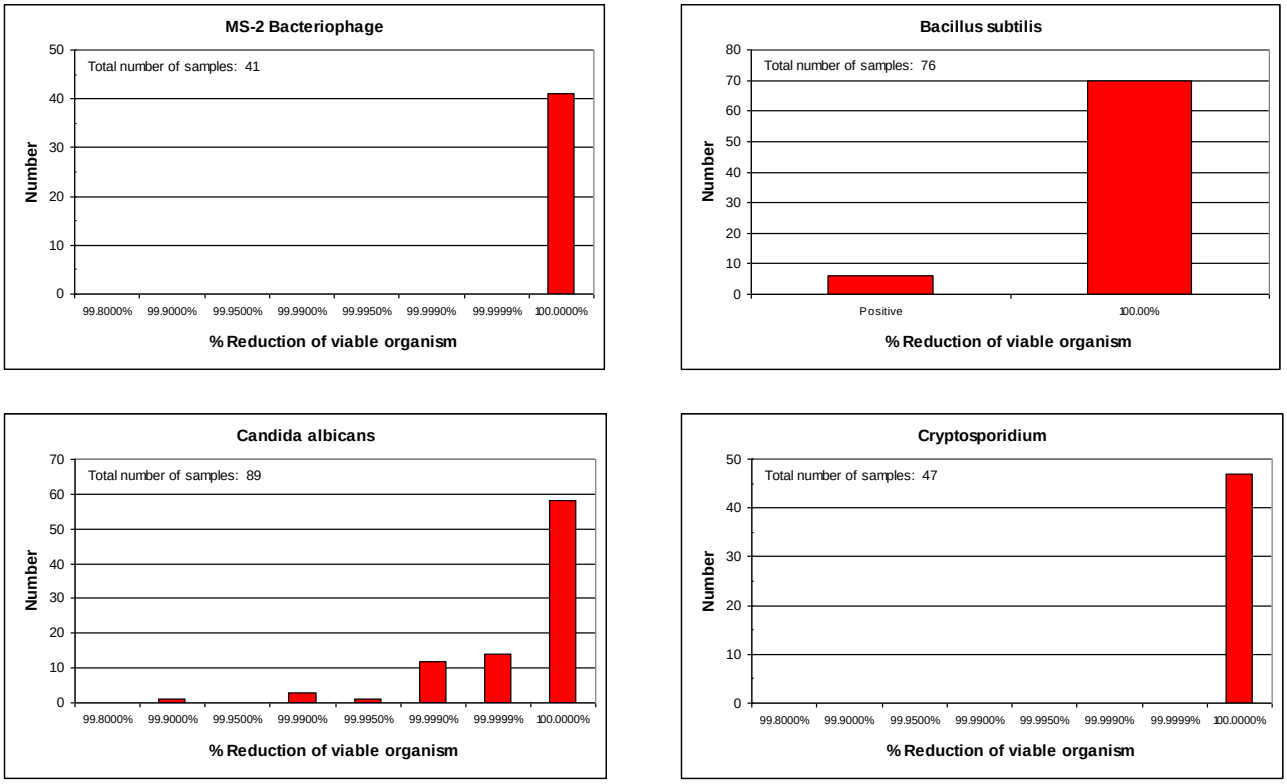

Figure 1. Results of microbiological validation of the Johannesburg plant.

Problems Experienced

The requirements for testing as specified by GDACEL, indicated the minimum test organisms and strains to be used for plant validation. However, for two of the organisms, the stipulated ATCC organism could not be obtained in South Africa. Therefore the organism strain closest resembling the required ATCC organism was used in testing. The American Type Culture Collection (ATCC) was approached to provide guidance on possible replacement organisms. It was therefore the opinion of the project team that the test organisms used for plant validation adequately approximated those stipulated by GDACEL and responded to the ETD™ process in the same way as the required ATCC organisms.

Since the correct ATCC *Bacillus subtilis* culture was not available in South Africa, the project team made use of the *Bacillus* indicator vial, imported from the USA. The *Bacillus subtilis* indicator vials (ATCC 9372), referred to as Allkil™ are specifically designed for the efficacy testing of non-burn treatment facilities. The vials provide quick and effective results, since the indicators are not plated out, but instead incubated immediately after processing. The limitations of the vials are however, that they only indicate a positive or negative result. It was therefore important to make use of an indicator with at least a 4 Log_{10} concentration of organisms. A negative result would therefore indicate 100% efficacy and a 4 Log_{10} reduction, as required.

For test organism, *Cryptosporidium*, a required 6 log_{10} reduction was specified by GDACEL. However, due to the lack of animal facilities in South Africa, equipped to do animal infectivity tests for *Cryptosporidium* oocysts (the preferred method to determine the Log_{10} reduction of oocysts), the percentage viability of the

Cryptosporidium oocysts was instead used. The feasibility of this change in method was discussed with representatives of the National Health Laboratory, and agreed upon to be an acceptable, alternative means of testing. The change in approach, meant that viable parasites needed to be used, which had to be imported from the USA. With the poor Rand-Dollar exchange rate, this had significant cost implications to the project and delayed the testing by approximately two weeks.

The results from runs 1-4, for *Candida albicans*, showed an average log reduction of 6.37 Log_{10}, but with values as low as a 3 Log_{10} reduction. An evaluation of the laboratory technique used for samples from runs 1-4 was made and it was decided to replace the Standard Streak Plate Method which had been used on these runs, with the Standard Membrane Filtration Method for two additional runs. The change in test method produced more accurate, repeatable results for runs 5-6, giving an average log reduction of 7.13 Log_{10} with no results below the required 6 Log_{10}.

Positive results for *Bacillus subtilis* Allkil™ were obtained from the initial 5 runs, which suggested ineffective treatment. However, duplicate samples incubated at the EMW treatment facility did not show any level of contamination. Discussions with BloCl Systems Inc., the producers of the Allkil™ vials, in America, indicated that the incorrect handling of the indicator vials, after treatment and during delivery to the laboratories, could result in 'contamination' of the samples, thereby producing false positives. According to BloCl Systems Inc., contamination can occur if the Allkil™ vials are not kept upright during transportation. Incorrect handling leads to the liquid within the vial (derived from crushing the first ampoule), wetting the cotton wool venting plug and contamination then 'wicking' through into the vial interior when the second (nutrient) ampoule is crushed prior to placing the vial in the incubator. An additional six runs of *Bacillus subtilis* were performed to test this theory. All samples were thereafter transported to the laboratory as per the manufactures instruction, and all produced negative results with 100% inactivation.

In addition, since indicator vials were used for *B. subtilis*, a positive result, could not be assessed in terms of the log reduction. The level of inactivation of any positive *B. samples* could therefore not be quantified.

CASE STUDY 2

Following the successful approval of their Johannesburg non-burn treatment plant, Evertrade Medical Waste submitted a request for approval of their Cape Town plant. The Western Cape Department of Environmental and Cultural Affairs and Sport adopted the relaxed requirements for validation. In their statement to EMW Operations, the Department requested that "*Validation of the total non-burn treatment process, in terms of the control and eradication of pathogens in the collection, treatment and disposal aspects of the project, must be conducted by a suitably qualified microbiologist prior to the first disposal of the final waste product, the results of such validation must be submitted to the Environmental Health Department of the Local Authority for acceptance*."

EMW Operations adopted a relaxed STAATT2 approach, as used in Japan. As with the Johannesburg plant validation, EMW Operations made use of the *Bacillus subtilis* Allkil™ indicators. The results of the validation testing programme showed 100% inactivation of *Bacillus subtilis* spores with the ETD™ process. The reduced testing programme had significant cost savings for the company and reduced the time required for testing by weeks.

Calibrated parametric monitoring, e.g. temperature, pressure, throughput, residence time etc, is an important management aspect for EMW Operations, in ensuring that health care risk waste is suitably treated in their facilities. It is however important to calibrate these parameters during the validation process, i.e. against results of microbiological testing, as well as on a regular basis.

TESTING STANDARDS AND PROTOCOLS

Due to the problems encountered in the evaluation and issuing of a Record of Decision for the Evertrade Medical Waste Treatment Facility, and to ensure a standard approach to the validation and efficacy testing of future non-burn treatment facilities in Gauteng, GDACEL commissioned Environmental & Chemical Consultants to evaluate the current approaches to validation testing. The deliverable was the Draft Testing Standards and Protocols for Non-burn Health Care Risk Waste Treatment Technologies (Baldwin, 2002). This report to GDACEL outlined the monitoring and testing requirements of non-burn treatment technologies and included four testing types:

- *Performance Testing* – such testing is required before an EIA is authorised by the Department, i.e. to prove efficacy of the treatment technology. The facility must demonstrate that it can meet the minimum standard for one or more of each of the microbial groups listed in STAATT1.

- *Regular Testing Programme* - Once the operation permit has been granted, a regular testing programme is implemented, for up to 12 months. The regular testing programme requires the testing of bacterial spores and Mycobacteria, at least once a month.

- *Reduced/Routine Testing Programme* - Once the plant has demonstrated that it can meet the criteria required by the Regular Testing Programme, the Department may permit a reduced frequency of analysis. Replacement of some or all of the sterilisation monitoring programme by parametric monitoring may be allowed provided the facility demonstrates that it has the appropriate controls and a quality management system in place.

- *Investigative Testing* – Should any problems be found in any of the testing programmes, the facility must immediately commence an Investigative Testing Programme. The requirements of the Investigative Testing Programme is the same as the Performance Testing Programme.

The Testing Standards and Protocols put forward in this draft document outline the following as the minimum testing requirements:

- A Level III inactivation must be attained as a minimum for all technologies, even those that treat and generate small amounts of waste and that may be designed for desktop applications or for applications in small clinics and/or rural areas. This requires an inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at ≥ 6 Log_{10} reduction; and inactivation of *B. stearothermophilus* or *B. subtilis* spores at ≥ 4 Log_{10} reduction.
- The performance testing programme must be carried out weekly for a one month period, i.e. at least 4 times, on "normal" infectious waste. The plant must also demonstrate that it can meet the programme on a challenge load.

As such, GDACEL adopted the standards and procedures developed by the State and Territorial Association of the USA (STAATT).

EVALUATION OF EFFICACY MONITORING REQUIREMENTS

To assess whether the standards proposed by GDACEL placed undue financial burden on new treatment technologies, GDACEL commissioned Environmental & Chemical Consultants and the CSIR to assess the costs associated with implementing the standard testing requirements for non-burn HCRW treatment technologies in Gauteng Province. A report was prepared for GDACEL in April 2003 (Godfrey & Baldwin, 2003) which outlined the:

- International and local approaches and standards
- Gauteng draft validation programme
    - Proposed monitoring programme: general assessment
    - Performance testing
    - Regular testing
    - Analytical procedures for efficacy testing
    - Availability of analytical facilities in South Africa
    - Availability of microbiological organisms in South Africa
- Cost of implementation
    - Testing costs for Large Commercial Facilities
    - Testing costs for Small on-site Facilities
- Alternative validation programmes
    - Proposed requirements
    - Estimated costs
- Comparative costs of various validation programmes

Based on a sampling frequency of 5 runs, of 10 samples per run (50) for large commercial facilities, and 4 samples per run (20) for small facilities, the following cost estimates were calculated.

Costs were prepared for two performance testing scenarios:

(1) Complete STAATT 1 testing
(2) Reduced STAATT 1, excluding parasites

and two daily monitoring scenarios:

(a) as per suggested Guidelines (Baldwin, 2000), i.e. once per day.
(b) as per draft Gauteng Guidelines, i.e. every 2 hours of operation.

Table 1. Summary cost for Performance and Regular Testing at small and large facilities.

Testing Programme	Cost [R]	
	Commercial Facilities	Small on-site Facilities
STAATT1: Performance Testing (1)	R260 800	R125 800
STAATT1: Performance Testing (2)	R190 800	R77 800
STAATT2: Performance Testing	R37 750	R15 100
Daily Monitoring (a)	R400 / m	R400 / m
Daily Monitoring (b)	R3 200 /m	R7 200 /m
Monthly Monitoring	R17 000	R7 000

* This costing excludes internalised costs to the treatment facility, such as HR, travel, operating costs, etc and should be seen as laboratory costs only.

From the costs given above, it is evident that the STAATT2 testing requirements are considerably cheaper than the STAATT1 requirements, without compromising the confidence in results obtained. In addition, daily monitoring (once per day) in conjunction with parametric controls, provides a more cost effective and time efficient approach to monitoring.

Performance testing option (2), i.e. reduced STAATT1, was included in the cost scenario, due to the technical constraints facing laboratories with regards to animal testing facilities. Also, from previous experience, the inclusion of parasites in testing added between 27-38% to the total cost, without increasing the confidence in the test results.

CHALLENGES

A number of challenges still face authorities, proponents and laboratories with regards to validation and monitoring of non-burn health care risk waste treatment facilities . These include:

- The limited availability of required ATCC organisms in South Africa;
- The requirements for the importation of viable *Cryptosporidium* oocysts for every validation test;
- The limited availability of accredited laboratories in South Africa;
- The limited availability of qualified individuals to supervise validation programmes;
- Interpretation of requirements from authorities;
- Interpretation of results by laboratories, the proponent and authorities;
- Lack of consistency between Provincial Authorities in their approach to the validation of non-burn treatment technologies;
- Lack of national guidelines for validation and monitoring.

CONCLUSIONS AND RECOMMENDATIONS

The work to date in developing Standards and Protocols to assist authorities and proponents, has in itself be a major success, simply by making information available. It is hoped that this information will be carried forward into the development of Guidelines or Minimum Requirements for the validation and monitoring of non-burn health care risk waste treatment facilities in South Africa.

With a number of challenges facing authorities, proponents and laboratories, it is hoped that capacity will be built within the country to adequately implement and assess testing programmes. It is also necessary that a 'library' of required organisms be created at an accredited laboratory within South Africa, to ensure that all test organisms (with the exception of parasites) are readily available, should validation testing be required. It must be noted that viable parasites can not be kept for long periods of time and would need to be obtained for each validation test.

With regards to the approach to testing, although STAATT 1 and 2 have provided a platform from which to assess efficacy testing of non-burn health care risk waste treatment technologies, it is evident that states within the USA have adopted varying approaches to assessing microbiological efficacy, ranging from the use of single indicator organisms such as *Bacillus subtilis*, to the full STAATT 1 list of organisms. However, in most instances where the STAATT 1 list of organisms is required, parasites, *Giardia* or *Cryptosporidium* have been excluded from testing. The use of parasites has proven to be difficult in evaluating medical waste treatment systems, since growth of the organism to a concentration that would meet the Level III inactivation criteria of STAATT 1 and 2 is not possible, and there are only a limited number of researchers internationally that have the expertise to work with parasites.

It is recommended that the frequency of regular monitoring be reduced to once a day, making use of bacterial spores either *Bacillus stearothermophilus* or *Bacillus subtilis*. With time this may be further reduced to once per week, or once every 40 hrs of machine operation. Every 2 hours or every batch is considered excessive, because of the increased cost and the loss in productivity of the plant. Greater reliance should be placed on parametric measures, which must be reported on and fixed during the validation process, and calibrated on a regular basis by means of test organisms. It should be noted that most modern processes are computer controlled and once the required process parameters are set, interference by the operator can either be prevented or, at least, would be recorded, thereby allowing the Department or Facility Management to take action. The required calibration frequency will depend on the technology.

Based on the technical support and the cost assessment of conducting a validation testing programme on a non-burn health care risk waste treatment technology, it is concluded that STAATT 2 is considered acceptable, and widely used for validation. However, should STAATT 1 be adopted, it is suggested that parasites be excluded from the testing programme. After approval of the technology, regular monitoring should be conducted daily for both batch and continuous processes, making use of bacterial spores *Bacillus stearothermophilus* or *Bacillus subtilis*.

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