Attachment D.2 – Facility Operation

The activities proposed for the site can be broken down into three main categories:

1. Waste Treatment Process and associated storage activities
2. Waste Transfer Process and associated storage activities
3. Waste Recovery Process and associated storage activities

D.2.a Waste Treatment Process

All waste treatment processes are undertaken within the building located at 430 Beech Road. The stages of the process are shown in the attached flow sheet figure D.2 F1 and described below.

Waste Reception

On arrival on-site, the vehicle carrying the waste reverses to the front door of the plant. The driver presents a member of plant staff with consignment notes for the waste and downloads waste details into the site computer system from his portable data unit.

The site operator checks to confirm that the information presented is correct and the driver offloads the vehicle. As each bin is off-loaded, it is scanned and weighed by the plant operator. The bin is placed into the holding area for processing.

If the waste is suitable for treatment, it is weighed and logged onto the system. Any waste received not matching the consignment note provided is placed into the quarantine store pending an investigation. If the waste is not suitable for treatment, it is transferred to the waste transfer process in the adjoining building.

Waste Storage

This part of the site has a capacity to hold up to 400 bins of waste. Bins are rotated through the site on a first in / first out basis. Personnel on site are able to interrogate the site's computer system to determine the total mass of waste on site, the total number of bins on site and length of time any particular bin has been on the site The maximum length of time that waste will be stored in this area is 72 hours.

Waste Treatment

The site currently utilises a modified Sterile Technologies Industries (USA) Series 2000 medical waste treatment system to disinfect healthcare risk waste. The Agency has agreed to the installation of a second independent processing line, which is currently being installed. The system will be fitted with identical abatement equipment to the existing system.

The stages of the system are shown in figure D.2 F2 and described below. A system schematic is shown in figure D.2 F3

The operator selects the bin for processing from the waste store. The bin is placed in the hoist and the operator pushes a button to lift the bin and empty it into a shredder. The empty bin is then lowered and scanned before being sent to the bin wash area for cleaning.

The system is designed to shred, disinfect and render unrecognisable all forms of healthcare waste not specifically requiring incineration. The system treats sealed containers and their contents. On entry into the treatment system, the lid of the shredder hopper automatically opens and the containers are tipped into the hopper. The lid automatically closes when the waste has been input. The waste drops into a shreddding chamber, fitted with a series of cutters mounted on shafts. Downward pressure is applied to ensure efficient introduction of the waste to the shredding mechanism. The waste is shredded to 'confetti-like' consistency prior to entry into the treatment auger. The system is enclosed and operates under negative pressure. Air is drawn through a HEPA filter prior to exhausting to atmosphere. The HEPA removal efficiency is not less than 99.95% for a maximum particle size of 0.3µm. An interlock prevents the introduction of waste unless the negative pressure system is functional.

Within the thermal treatment section of the process (the auger), low-pressure steam is injected from multiple ports on the side of the auger and from a central column running through the core of the auger screw. The number and position of the injection ports are designed to provide effective coverage of the waste with steam. In addition, mixing tabs in the auger mix the waste to enhance the permeation of steam through the confetti-like material. Integral thermocouples are used to maintain the operational temperature within the 97^0C – 111^0C range. The material passes into the steam-jacketed portion of the auger that raises the temperature above 100^0C and evaporates moisture from the waste. A vent is installed at the end of the auger to create a low pressure chamber in which moisture flashes to steam and is exhausted through a condenser and coalescing vessel where VOC's present are absorbed by the filter and odour is reduced to a minimum. The entire auger process takes between 75 to 85 minutes.

Daily microbiological testing has proved the efficacy of the system in the current plant. The STI process does not involve any combustion. The resultant waste product – known as 'flock' - is reduced in volume by a ratio of approximately 7:1. This unrecognisable treated waste is currently consigned to landfill. However, it is intended in the future that this 'flock' will be diverted to the adjoining building, 420 Beech Road, for separation and reclamation of paper, plastics, glass and metals.

Installation of Second Treatment Line

The Agency has agreed to the installation of a second independent processing line, which is currently being installed. This will have the capacity to process 1.5 tonnes per hour, giving a total capacity of 2.5 tonnes per hour for the site.

The new system is the latest version of the STI Model 2000 process and differs from the original in that significant improvements have been made in the areas of temperature control and electronic parametric monitoring. The unit itself is constructed of stainless steel, an improvement on the 'mild steel' construction of the original.

Included in this review are two reports to support our commissioning and on-going validation of the STI Model 2000 system. The first of these is the STAATT 11 report summarised below.

The State and Territorial Association on Alternate Treatment Technologies – STAATT 11

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 healthcare waste treatment process can be licensed. This report defined four levels of microbial inactivation (1 to 1V).

Since 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 produced which included several modifications to the original in the light of new knowledge. STAATT 11 Report is contained as attachment D.2 D2.

Our original licence application was based on STAATT 1. Our request for licence amendments is consistent with STAATT 11.

The second report has been compiled by Dr. Malcolm Holliday, FIBMS. MSc. PHD. MBA, an international expert in the field of alternative treatment technologies for healthcare waste. Dr. Holliday has successfully commissioned 23 separate 'alternate' non-burn healthcare waste treatment facilities and is a member of the National Specialist Advisory Panel for the Institute of Biomedical Sciences amongst others. This report, referencing STAATT 11 (the American team of experts of worldwide reputation who are regarded as the producers of the most significant and most widely accepted guidance on the management of healthcare waste facilities), is contained as attachment D.2 D3.

Given the successful operation of this system over the last 5 years with intensive monitoring of the STI Model 2000 at this facility by the Agency, it is proposed that commissioning tests will be limited to microbiological indicators and continuous parametric monitoring. This view is supported by Dr. Malcolm Holliday in his report. The commissioning tests proposed are designed to validate the quality and effectiveness of the installation works rather than to prove a new technology.

The following commissioning method is proposed;

- Twice-daily challenge testing using *Bacillus Atrophaeus* (formally *Bacillus subtilis* var. *niger)* as the indicator organism, testing to 6 Log^{10} reduction. These tests will be carried out for a period of one week.

- Continuous parametric monitoring in accordance with Condition 5.18 of Licence 55-1.

In accordance with condition 5.13.2 details of the commissioning test results will be forwarded to the agency under separate cover. However, processed waste will not require export. Should a batch fail will be reprocessed through the existing processing channel.

In support of parametric monitoring, the following conditions will be adhered to;

- The process will have tamper-proof controls with authorised access limited to Senior Management only.

- Monitoring will 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.

- Continuous recording of the critical operating parameters will be available on memory card or disc drive as an upgrade from previous paper / chart records.

STAATT 11 states that – "If a technology effectively demonstrated 4 and 6 log^{10} reductions of biological indicators within three different surrogate test loads under specific parameters, e.g. 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".

STI propose a further enhancement to the above monitoring with the demonstration of microbial inactivation not less than once weekly using *Bacillus Atrophaeus* ATCC 9372. After 6 months operation this frequency will be reduced to not less than once monthly for both processing channels. This is in line with Dr. Holliday's report.

Residue Storage

Flock is collected as it emerges from the end of the steam-treatment process. It will follow one of two routes;

1. It will be collected in flexible IBC bags. When a bag becomes full, it will be moved by forklift to a roll on-off container for disposal at landfill or;

2. It will be conveyed to the adjacent building, 420 Beech Road, for waste recovery and drying.

Before the flock can be moved off-site for disposal to landfill (or other suitably licensed facility), or subjected to further recovery it is held for 48 hours awaiting the outcome of efficacy tests.

Process Efficacy / Laboratory

Prior to the process residues (flock) being moved off-site, the efficacy of the process is determined to ensure the waste has been appropriately treated. The efficacy of the process is determined by:

1. Daily use of heat resistant bacterial spores *Bacillus Atrophaeus* ATCC9372 (formally *Bacillus subtilis* var. *niger*) to a $10\log_6$ reduction and;

2. Twice-weekly testing of 'grab samples' – analysis of the residual 'flock' for the presence of specific organisms.

Both forms of testing are currently conducted and verified by an approved independent Laboratory. Waste is held on-site in skips for 48 hours awaiting verification of test results from the laboratory. Once the laboratory test results have been received, skips are transported to landfill for final disposal.

The reliability of inactivation has been demonstrated through 5 years of operation. STI request that microbial inactivation be demonstrated not less than weekly using bacterial spores.

The independent microbiological efficacy tests that have been carried out over the last 5 years on the STI Model 2000 system have conclusively proven that the system consistently achieves the required treatment level with the stated operating parameters. This regime is far more thorough than that required by international guidelines.

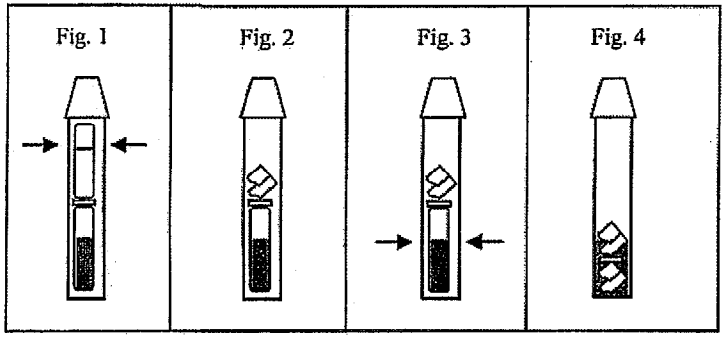
STI proposes to change to a new method of loading the biological indicator, which consists of the spore *Bacillus Atrophaeus*. This type of self-contained biological indicator (SCBI) eliminates any risk of self-contamination of tests (*Bacillus Atrophaeus*). This procedure will take over when the current stock of spore stripes is consumed. This challenge will be performed in the on-site laboratory with consistent with procedures previously approved by the Agency with the exception that a trained STI staff member will conduct the tests. The Certificate of Analysis for this system is included overleaf.

ALLKIL-SH-1™ Self-contained Biological Indicator
for Medical Waste Decontamination by Steam Heat

For use in steam heat decontamination process of up to 100°C for up to 2 hours

INSTRUCTION FOR USE

1. Hold self-contained biological indicator (SCBI) in upright position. Squeeze upper portion of device to crush the wetting agent ampoule (Fig. 1), releasing the wetting agent to saturate the spore disk (Fig. 2).
2. Place SCBI in the processor at the desired location and initiate the treatment process.
3. After the process is completed, remove SCBI from the processor and allow it to cool prior to handling.
4. Hold SCBI in upright position. Squeeze lower portion of device to crush the culture medium ampoule (Fig. 3).
5. Tap the device lightly to ensure that the spore disk is submerged in the culture medium (Fig. 4).
6. Incubate the SCBI in upright position at 30-39°C for at least 48 hours prior to result readout. Continue to incubate SCBI for up to 7 days. Dispose positive SCBI immediately.



RESULT READOUT

NEGATIVE read-out = no change in culture medium appearance after incubation. Decontamination was successful

POSITIVE read-out = culture medium turns yellow and/or turbidity after incubation. Decontamination was incomplete.

DISPOSAL

Dispose positive SCBI immediately as microbiological waste.

ALLKIL-SH-1
Self-Contained Biological Indicator

CERTIFICATE OF ANALYSIS

Test Organism:	*Bacillus atrophaeus* (ATCC 9372) (formerly *Bacillus subtilis* var. *niger)*
Nominal population (CFU):	2.1×10^6
D-value (moist heat):	5.4 min
Lot No.:	011206-e6
Expiration Date:	Oct. 2002 (02-12-06)

Example

D-value was determined by survivor curve method under 95-100°C flush cycle in a steam BIER vessel.
Population was determined using tryptic soy agar culture medium under 30-39°C incubation condition for up to 48 hours.
D-value and population are reproducible only when SCBI is exposed and/or cultured under manufacturer's testing conditions.

STORAGE CONDITION

Store under cool and dry condition away from aggressive chemicals or sterilization agents. Do not use after the expiration date

BIoCI Systems, Inc.
1220 Corporation Parkway, Suite U.
Raleigh, NC, 27610 USA
Phone: 919-235-0596
Fax: 919-235-0597
E-mail: inquiry@bioci.com
WebPages: www.bioci.com

Quality Certification Bureau Inc.

Accredited by the Dutch Council for Certification

BIoCI Systems, Inc.
ISO 9001 registered. Certification No. 01-1589

STI request the removal of the 'grab sampling' tests carried out on the treated waste, as the biological indicator testing is sufficient at set parameters to ensure inactivation. Science has proven that bacillus species is the most resistant of all microbial life to disinfection and destruction by both thermal and chemical methods. Demonstration that the highly resistant spores from the bacillus species can be effectively destroyed ensures a margin of safety beyond the inactivation of vegetative bacteria, fungi, viruses, parasites and mycobacteria. Because Bacillus spores are so much more resistant than all the other microbial groups, the margin of safety is much greater than required. *P. Aeruginosa* is the vegetative bacteria tested for in the grab samples and is very low on the Microbial Pyramidal Life, therefore inactivated easily.

The Microbial Pyramidal Life is attached as D.2 D3

STI request removal of the need for 'Annual Process Efficacy testing' as the plant has proven it consistently and reproducibly meets the required standards. Results of microbial testing prove quantitatively and qualitatively the level of microbial destruction. Apart from being prohibitively expensive, the test is essentially redundant as results are consistently documented throughout each year since operation commencement.

Bin Washing

Once a bin has been emptied, it is moved to the bin washing area. The site uses a custom-built bin-wash system to disinfect bins before return to customer sites. The system utilises a disinfectant detergent and hot water to remove all contamination from both the inside and outside of the bins and to render the surface of the bin disinfected.

The heated water and detergent are re-circulated within the bin wash with a small purge made on a regular basis to foul sewer. The steam generated by the bin-wash process is exhausted outside the building (Release Point A2-5) A small filter collects debris from the wash water preventing it being discharged to sewer. The collected debris is passed through the treatment process with the healthcare waste to ensure it is rendered safe.

When the second treatment line is operational, the capacity of the existing bin-wash system will be modified to improve the cycle time and throughput of bins. This will be achieved by re-programming the wash cycle. Elements of idle-time in the cycle have been identified and these will be minimised or eliminated in order to achieve the desired throughput and effectiveness of the process.

D.2.b Waste Transfer Process

All waste transfer processes will be undertaken within the building located at 420 Beech Road. The process undertaken can be broken down into the following unit operations:

Waste Reception

On arrival on site, the vehicle carrying the waste reverses to the front door of the plant. The driver presents a member of the plant staff with consignment notes and downloads details into the site computer system from his portable data unit.

The site operator checks to confirm that the information presented is correct and the driver begins to offload the vehicle. As each cage is off loaded, it is scanned and weighed by the plant operator. The cage is placed into storage.

Waste is also received from the quarantine store in the adjacent building at 430 Beech Road. This waste is that which the site is licensed to receive but which is unsuitable for the waste treatment process.

Any waste received that does not match the consignment note provided is placed into the quarantine store pending an investigation. If the waste is suitable for transfer, it is weighed and logged onto the system.

Waste Storage

This part of the site has a capacity to hold up to 400 bins of waste. Also located in this area are large chest freezers for the containment of anatomical waste prior to shipment for incineration.

Cages of waste received for storage are segregated based on their contents. Bins containing rigid one-way containers of anatomical waste or other wastes, which are likely to give rise to odours, are decanted into the freezers. The rigid one-way containers are marked with the date the waste is received and the consignment note number to aid traceability. A log of waste placed in each freezer is maintained to ensure that waste is rotated. All other cages of bins are placed into storage.

Cages are rotated through the site on a first-in first-out basis. Personnel on site are able to interrogate the site's computer system to determine the total mass of waste on site, the total number of cages on site, and the length of time any particular cage has been on the site. The maximum length of time waste will be stored in this area is 42 days though generally waste will not be stored for longer than 14 days.

Waste Repacking and/or Over-packing

Once sufficient quantities of waste have been received, the waste on site will be prepared for transport. A cage of waste will be selected on a first-in first-out basis. The cage is scanned and the contents of the cage stacked onto a pallet. This procedure is repeated until the desired pallet weight

and volume is achieved. The complete pallet is wrapped in plastic to ensure its stability during transport to the ultimate disposal facility.

If any waste container (sharps box, rigid one-way container, or similar) is found to be damaged and poses a risk of leakage during transport it will immediately be stabilised and over-packed into a suitable rigid container prior to placement on the pallet.

Waste Dispatch

Once the waste has been assembled onto pallets, the pallets will be loaded onto a lorry for transport/onward shipment to the ultimate disposal facility. The weight of the consignment will be calculated from the total weight of the each cage received by the site that has been assembled onto the pallets. The weight of the consignment will be entered into the site's computer system and deducted from the waste in stock on the site.

The waste will be accompanied with the appropriate documentation for transport under the Transfrontier Shipment of Waste Regulations.

D.2.c Waste Recovery Process

All waste recovery processes will be undertaken within the building located at 420 Beech Road. The process undertaken can be broken down into the following unit operations:

Waste Reception

The Waste Recovery Process receives only plastic waste. The other processes described above receive all healthcare risk waste. On arrival on site, the vehicle carrying the plastic waste reverses to the front door of the plant. The driver presents a member of the plant staff with the consignment notes and enters the plastic waste delivery details into the site computer.

The site operator checks to confirm that the information presented is correct and the driver begins to offload the bins from the vehicle. The plastic waste is weighed and scanned by the plant operator. The bins are placed into storage for processing.

Any waste received that does not match the consignment note provided is placed into the Waste Transfer Process quarantine store pending investigation. If unsuitable to be used in the recovery process, it is returned to the waste producer.

Waste Storage

The waste storage area will consist of two sections. One section will hold the plastic waste received for blending. The site will use a log sheet to identify which bags of flock relate to waste processed on

individual days. It is envisaged that the treated waste will be normally conveyed from the treatment process to the recovery process automatically through a conveyor. If an occasion arises whereby the waste must be manually input into the process, the flock will be held within the confines of the area in 420 Beech Road. This should only occur on rare occasions and will not be the normal operation.

The reclaimed materials will be held on site for the determined period to ensure efficacy prior to movement.

Waste Recovery

The stages of the waste recovery operation are yet to be finalised but are likely to include the steps detailed below;

Treated flock will be conveyed from Unit 430 Beech Road to Unit 420 Beech Road through an automatic conveyor where it will be discharged into the hot water float tank. In the hot water float tank plastics will rise to the top and be carried over into a dedicated plastics separator, which will allow water to be returned to the hot water float tank. The water in the hot water float tank is heated using steam passing through coils within the tank.

Paper and textiles, metal and glass will sink to the bottom of the hot water float tank and will be carried in the underflow to the belt press. The belt press removes up to 90% of the water that has been absorbed into the paper and textiles component of the waste. The water removed in the belt press is piped to the water treatment tank. When the waste leaves the belt press it passes through a magnetic separator, which removes the metal component of the waste. The waste then passes to a hot air dryer / classifier. In the hot air dryer / classifier, ambient air is passed over steam-heated coils to heat the air. The air is then blown through the waste drying it and separating it at the same time into light paper / plastic film, heavy paper / textiles and glass.

Air from the dryer containing the light paper and plastic film passes into a cyclone where the light paper and plastic film is removed from the air stream. A reverse jet pulse filter is used to remove any fine particulates and dust from the air stream before being vented to atmosphere via an exhaust fan.

The separated plastics, paper and textiles are bagged off as they are collected from the individual steps of the process. Metal and glass are collected in suitably sized mini-skips or FIBC bags. The hot water in the float tank, together with the water recovered from the belt press and plastics area is returned to a central water treatment tank. The water in the water treatment tank is filtered to remove suspended solids and dosed with sodium hypochlorite to prevent bacterial growth. A pump re-circulates the water to the hot water float tank.

Make-up water is added to the water treatment tank as required and water is purged from the tank to sewer after passing through a solid strainer.

The only emissions from the process are to air from the cyclone via the reverse jet pulse filter and to sewer from the water treatment tank purge.

Residue Storage

Once the recovery process has been completed and the components of treated healthcare waste have been separated into their reusable components, these will be contained in a bagging system similar to that in the Waste Treatment Process where the residues will be packed into flexible IBC bags.

Separated waste will be taken off-site to an appropriate licensed facility for manufacture into reusable components or for disposal at a landfill.

Document D2.D1. State and Territorial Association on Alternate Treatment Technologies (STAATT 11)

Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies

A Report of the State and Territorial Association on Alternative Treatment Technologies (STAATT)

TR-112222

Final Report, December 1998

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REPORT SUMMARY

This report presents the results of the second STAATT conference for the discussion of important issues associated with the regulation of medical waste treatment technologies.

Background

The first STAATT report was made available to state and federal regulators and treatment technology vendors in 1994. This second STAATT report is an attempt to expand on some of the issues that were addressed in the first report and to clarify some of the points that had been left unsettled at the time of publication of the first report.

Objectives

The main purpose of this report is to propose standardized criteria for efficacy of medical waste treatment technologies, and to suggest the essential components of an effective state approval process for medical waste technologies.

Approach

There are four main issues that are addressed in this report:

- Efficacy assessment criteria for alternative medical waste treatment technologies
- Approval processes for alternative medical waste treatment technologies
- Permitting and state authorization issues
- Research and development

Recommendations for future activities are also addressed.

Results

Participants at this meeting agreed that an information clearing house should be created to maintain and update information about the following:

- The participants attending the meetings and the agencies they represent
- All present medical waste treatment technologies that are commercially available
- Medical waste treatment technologies that are no longer commercially available
- New or modified state and federal regulations related to medical waste
- OSHA requirements for worker safety
- FIFRA registration of chemicals approved for use in chemical medical waste treatment

Participants also agreed that the use of biological indicators should be modified in the following ways:

- Mandatory efficacy testing should be limited to *Mycobacterium spp.* and *Bacillus* spores
- The reduction levels required for these two organisms should remain at their current levels
- These biological indicators should be included in the surrogate test loads for initial efficacy tests of treatment systems

In addition, the participant came to the following conclusions about testing and treatment of medical waste:

- Treatment technologies should be initially evaluated through the use of actual treatment systems rather than "bench top" testing
- Technologies should be tested with loads equal to the systems' treatment capacities
- Once a technology has met initial efficacy test requirements, additional testing with biological indicators should no longer be required
- Microbiological waste should be treated on-site, as it is the most dangerous type of medical waste
- Treated waste should not need to be monitored for microorganisms

Finally, the following observations were made about medical waste treatment in general:

- Efficacy testing is merely one factor in the safe and effective treatment of medical waste
- If chemical alternative treatment systems are used, the chemical should be certified under FIFRA as effective in the treatment of medical waste
- Other components of treatment technologies, such as engineering control, operator safety, and ergonomics, should also be evaluated

EPRI Perspective

EPRI Healthcare Initiative (HCI) is a collaborative effort of over 70 electric utilities. Its purpose is to meet the ever-changing demands of the healthcare industry through electrotechnology solutions that will reduce risk and liability, meet regulatory compliance demands, and ultimately provide the highest level of quality patient care. This publication helps document medical waste issues and will help electric utilities understand how various technologies, many of which use substantial electricity, can be used to deal with the problem.

TR-112222

Interest Categories

L3005 Healthcare

ACKNOWLEDGMENTS

The first STAATT report was prepared by Dr. Nelson S. Slavik, Environmental Health Management Systems, Inc. South Bend, Indiana, under contract to Science Applications International Corporation under Prime Contract EPA 68-WO-0027, Subcontract No. 36-930040-68.

The second STAATT report (STAATT II) is a modification of the original document containing the revisions that resulted from the STAATT II meeting held in New Orleans, Louisiana, February 15 and 16, 1998. The STAATT II document narrative is derived primarily and unrevised from the original document. Participants listed in Appendix D of this document contributed to the modifications in STAATT II. Ira Salkin, Ph.D., New York State Department of Health and Edward Krisiunas, MT(ASCP), CIC, MPH, Spectrum, Burlington, Connecticut served as co-facilitators of the meeting.

The STAATT II project was managed by Spectrum under contract to EPRI.

CONTENTS

LIST OF TABLES

EXECUTIVE SUMMARY—STAATT I (APRIL 1994)

Introduction

The purpose of this report is to establish guidelines that define medical waste treatment technology efficacy criteria, and to delineate the components required to establish an effective state medical waste treatment technology approval process. The recommendations made in this report are an attempt to find commonalty on many of the issues and criteria required in the medical waste treatment technology review process. Recognizing that all states may not totally agree with these recommended criteria or protocols, the guidelines developed should serve only to provide guidance to the state in the development of an approval process for alternate medical waste treatment technologies.

The establishment of qualitative and quantitative parameters that ensure effective and safe medical waste treatment are required in defining treatment technology efficacy criteria and delineating the components necessary to establish an effective state medical waste treatment technology approval process. Recommendations are provided in this report for the following:

- Alternative medical waste technology efficacy assessment
- Alternative medical waste treatment technology approval process
- Permitting and site authorization issues
- Research and development

Alternative Medical Waste Technology Efficacy Assessment

This report recommends that all emerging alternate medical waste treatment technologies should, at a minimum, be capable of causing the inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of *Bacillus stearothermophilus* spores or *Bacillus subtilis* spores at a 4 Log_{10} reduction or greater.

In meeting this criteria, selected pathogen surrogates which represent vegetative bacteria, fungi, parasites, lipophilic/hydrophilic viruses, mycobacteria, and bacterial spores are

recommended. Formulas and methods of calculations are recommended for the enumeration of medical waste treatment efficacy and are based on microbial inactivation ("kill") efficacy as equated to "Log_{10} kill" which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment.

Alternative Medical Waste Treatment Technology Approval Process

This report recommends that both state and site approval be attained for the use of any emerging alternate medical waste treatment technology. Specific recommendations are provided for:

- State approval requirements of the technology to ensure that the technology is effective in safely inactivating microorganisms to specified criteria
- Site approval requirements to verify that the sited equipment meets approved specifications and treatment efficacy requirements under actual operating conditions
- U.S. EPA pesticide registration requirements, as applicable, for those medical waste treatment technologies that use chemicals as the microbial inactivator

Additionally, the report recommends that parametric monitoring of the treatment process can substitute or replace biological indicator monitoring provided certain verification and monitoring parameters were achieved.

Permitting and Site Authorization Issues

Several permitting and state authorization issues relating to alternate medical waste treatment technology approval are identified and discussed. Recommendations are provided for the following issues:

- User verification treatment efficacy monitoring
- Commercial versus on-site facilities
- Previously approved technologies
- Small medical waste treatment devices
- Waste residue disposal

- Operator training
- Equipment operations plan
- Emergency and contingency response plan

Research and Development

This report recommends that each state view as optional its participation in experimental medical waste treatment research and development projects. For those states opting to participate in medical waste treatment technology research and development projects, issues recommended to be considered are the following:

- Process of establishing research and development variances, including imitations and allowances
- Potential environmental emissions and occupational exposures
- Treatment process residue disposal
- Agency funding and staffing

This report also provides supplementary materials to assist the state in developing guidelines, an information request form, and treatment efficacy testing protocols. These materials are located in the Appendix under the following headings:

- State Guideline for Approval of Alternative Medical Waste Technologies
- Application for Evaluation and Approval of Medical Waste Treatment Technology
- Example: Treatment Efficacy Testing Protocol for a Grinder/Chemical Medical Waste Inactivation Process

EXECUTIVE SUMMARY—STAATT II

(DECEMBER 1998)

Meetings were held in New Orleans, LA with state and federal regulators (see attached list of participants) on February 15 and 16, 1998 to discuss the revisions which should be made in the initial STAATT guidance document published in April, 1994. The following are the more significant decisions reached at the meeting:

It must be noted that all recommendations represent a consensus of opinion, not necessarily unanimity, of those in attendance. Further, the recommendations were made by the participants in their capacities as recognized experts in the field and do not necessarily represent the policies or recommendations of any of the state or federal agencies that the participants represent. The final document should represent a guide to the methods and procedures to be used in the evaluation and approval of conventional and alternative medical waste treatment technologies. It is not intended to be used, either in whole or part, in the development of statutes or regulations;

A table should be prepared and placed in an appendix that contains the names and address of all participants attending the meetings, the agencies they represent, etc., to be used by commercial manufacturers and public interests groups, to establish contacts in the appropriate regulatory organizations;

It was the opinion of those present that a second table be created and placed in the appendix that lists all present technologies which are commercially available, the states in which they have been approved for operation, the states in which they have been sited, the number of units that are in operation in each of the states, and the states in which the commercial vendors have applied for approval to site their technologies;

In addition, it was recommended that a separate third table be developed which would indicate technologies which are no longer commercially available and should be eliminated from the vendor lists maintained by state and federal regulatory agencies;

It was also suggested that these tables be maintained and updated by an information clearing house (see discussion of clearing house) on a regular basis, e.g., every six months to one year, through means of electronic communications with state and federal regulatory agencies;

All participants agreed that an information clearing house was an excellent proposal and that a contact name, postal address and electronic communication methods with this clearing house be prominently presented in the STAATT II guidance document. In addition to regularly updating the information contained in the tables described above, the clearing house could periodically provide information on new or modified state and federal regulations related to medical waste, OSHA requirements for worker safety and the FIFRA registration of the chemicals (pesticides) approved for use in chemical medical waste treatment systems. For the present, the clearing house should continue to be located within the South Carolina Department of Health and Environmental Protection under the direction of Phillip Morris;

However, it should be noted that Kristina Meson strongly suggested that STAATT submit an application to the federal Environmental Protection Agency to obtain funds to maintain the operations of the clearing house and to expand its current role. It was suggested by several of the participants that STAATT also establish a national certification program similar to those conducted by national regulatory agencies. In such a situation, STAATT would evaluate the initial efficacy test data provided by manufacturers of treatment systems and certify technologies as having been STAATT standards. The EPA funds, if obtained, could be used to fund these activities as part of the functions of the information clearing house. While individual states would be free to apply more stringent requirements, the STAATT certification would indicate that treatment systems have met prescribed base-line requirements. This should simplify the approval procedures for manufacturers and provide states without medical waste treatment review program with a means of insuring that such treatment systems sited within their states are capable of effectively treating medical waste;

If such a STAATT certification program could not be implemented, then the participants recommended that the guidance document contain a table in the appendix that lists the names and address of three or four laboratories that could be used by all manufacturers to conduct efficacy tests for all state regulatory agencies. The participants agreed to provide lists of the laboratories which have conducted such testing of treatment technologies for their own states regulatory purposes;

It was the consensus of opinion that the use of biological indicators be modified in several ways. First, the number and diversity of such indicators used in initial efficacy tests should be reduced to *Mycobacterium spp.* and *Bacillus* spores. It has become apparent in the tests performed with many different technologies as required by state regulatory agencies, that the use of additional biological indicators

provides no additional safeguards to public health and safety by further insuring the efficient operations of treatment systems. However, they do significantly add to the costs of efficacy tests conducted at independent laboratories funded by the manufacturers;

Second, the currently required long list of biological indicators and their associated ATCC accession numbers should be included in a separate table in the appendix of the final document. Manufacturers would be free to include these other indicators, e.g., bacteria, fungi, viruses, but would not be required to use them in efficacy tests to meet state requirements;

Third, the guidance document should continue to recommend a 6 Log_{10} reduction in the concentration of *Mycobacteria*, e.g., *M. bovis* BCG, *M. phlei* or other species of mycobacteria and a 4 Log_{10} reduction in the level of *Bacillus* spores. The participants believed that the factors which contributed to the initial recommendations to achieve these Level III inactivation parameters were still valid and should be included in the revised guidance report;

Fourth, the biological indicators should be included in the surrogate test loads for initial efficacy tests of treatment systems. Spiking the waste with suspensions containing high concentrations of the indicators is not recommended because these suspensions tend to pool at the bottom of the waste loads. However, there are numerous methods which can be used to add the indicators into the loads, even in tests of systems which grind waste prior to treatment and/or do not have "test" ports to add the indicators during the routine operations of the technologies. For example, one can adhere *Bacillus* spores to brightly colored paper which after shredding and treatment, could be easily detected in the treated waste. Alternatively, one can seed cotton balls with the indicators, place the balls into open-ended plastic tubes of a sufficiently small enough size that they would pass through the shredder blades. These sorts of novel and creative approaches permits the addition of the indicators directly into the test loads. Under no circumstances should the indicators be enclosed within sealed plastic or mental tubes. If such tubes were used with a heat treatment system, the conditions within the tubes would not be similar to those within the waste loads and would not be reflective of the actual treatment capabilities of any treatment system;

Since the number and diversity of biological indicators is to be reduced, it would not place an undo burden on manufacturers to conduct initial efficacy tests of their technologies with a minimum of three surrogate test loads which differ in the concentrations of organic to non-organic compounds and fluid to solid components;

Second, the consensus of participants was that all technologies should, whenever possible, be initially evaluated through the use of the actual treatment systems. "Bench top" testing to simulate the conditions during the treatment of waste in the

actual systems would be unacceptable. The participants agreed that this type of testing could never truly reflect the many variations found in the treatment of waste with the actual treatment systems. However, the participants did acknowledge that technologies may be developed in the future which could only be tested through the use of controlled, laboratory procedures and in such circumstance bench top tests might be acceptable;

Third, the participants agreed that conventional and new technologies should be tested, whenever possible, with surrogate test loads equal to the systems' treatment capacities. If a treatment system has the capacity to treat 400 lbs. of medical waste per cycle, then the initial efficacy tests should be conducted with "spiked" 400 lbs. surrogate test loads. The physical dynamics within a system which directly effect its treatment capabilities are altered by the volume of waste being treated. A system rated as treating 400 lbs. of waste per cycle will most effectively treat 400 lb. loads of medical waste;

Fourth, 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 no longer be required. The parameters recorded during initial efficacy tests would be used to validate the system once cited and for quality control purposes. If a technology effectively demonstrated 4 and 6 Log reductions of biological indicators within three different surrogate test load under specific parameters, e.g., 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;

Fifth, it was the opinion of the participants that the waste generated by clinical microbiological laboratories constitutes the most dangerous portion of the medical waste stream. Therefore, the participants recommended that all microbiological waste be treated on-site by either conventional or alternative technologies. Even if facilities contract to have medical waste hauled from their laboratories for treatment and disposal, it was the advice of all present that microbiological waste not be included with this untreated waste. Microbiological products should be treated on-site and then discarded with the routine non-medical solid waste to be handled by solid waste haulers for eventual disposal in a sanitary landfill;

Sixth, it was the consensus of the participants that "treated" waste need not be monitored for microorganisms. The most appropriate method for evaluating the efficacy of treatment systems is either through the use of biological indicators such as bacterial spores (*Bacillus spp.*) or parametric monitoring that has been correlated with acceptable levels of microbial inactivation. As has been discussed in previous meetings, the use of the terms sterilization and disinfection are not as easily applied to the treatment of medical waste as they are to medical devices. Medical waste

treatment systems should achieve an acceptable level of microbial inactivation, that is, a consistent reduction in the concentration of viable microorganisms. Low levels of microorganisms which may be found in treated waste are not likely to constitute a danger to the public's health and safety. Furthermore, the treated waste would routinely be taken to a sanitary landfill for disposal. The conditions within such a landfill are not conducive to the growth of most human pathogens. Given all of these factors, the participants agreed that treated medical waste need not be tested for the presence of viable microorganisms;

The participants all noted that efficacy testing is only one factor in the safe and effective treatment of medical waste by conventional or new technologies. First, facilities generating medical waste must evaluate their current waste streams in order to minimize the medical waste components of their solid wastes, more effectively manage the processing and transport of the medical waste within their facilities and insure that all medical waste is appropriately packaged for internal and/or external transport;

Second, if chemical alternative treatment systems are used, the chemicals should be certified under FIFRA as effective when used in the treatment of medical waste. The EPA has begun to evaluate many of the chemicals employed in new technologies as being usable to treat medical waste. The regulators with the EPA believe that many, if not all of the chemicals used in treatment systems will be evaluated by the end of this year;

Third, other components of the treatment technologies should also be evaluated, including engineering controls, operator safety, ergonomics involved in the operation of the systems and similar factors. For example, if the treatment system utilized a HEPA filter, the fittings of the filter should be inspected, the filter should initially and at regular intervals be challenged with DOP tests, parametric controls which provide the operator with visual indicators of filter operation should be periodically evaluated for accuracy;

This summary will serve as a guide in revising the initial STAATT document to create the STAATT II guidance report. Copies of this executive summary will be circulated to all participants to obtain their recommendations and suggestions of other significant issues to be included in the STAATT II document.

1

INTRODUCTION

The development of new medical waste treatment methods utilizing heat, chemicals, heat/chemicals, or irradiation has provided potential alternate solutions to the medical waste treatment/disposal problem. However, with the development of these emerging medical waste treatment methods, has arisen the concern that the use of these new technologies may lead to potential environmental or occupational health and safety problems. While several states and federal agencies have attempted to quantitatively and qualitatively assess the efficacy and safety of these new treatment systems, there is no universality in the approach undertaken by these regulatory agencies.

The establishment of uniform guidelines or standards for evaluating alternative treatment technologies at the first set of meetings in the early 1990s of the State and Territorial Association on Alternate Treatment Technologies (STAATT) was considered essential to establishing the following benefits to both regulators and manufacturers:

- Scientifically valid evaluation criteria
- Elimination of costly state-by-state approval procedures
- Minimization of individual state liability for review and evaluation methods
- Enhancement of information exchange among state and federal regulators
- Creation of an information "clearing house" on regulations and new technologies

Although these first meetings and the resulting publication of the STAATT Technical Assistance Manual did contribute, over the intervening years, to bringing several of these benefits to fruition, many of the issues remained unresolved. Consequently, a second set of meetings was held, with the assistance of EPRI, in New Orleans on February 15 and 16, 1998 to address many of the same following topics as in STAATT I:

- Definition of the level of recommended microbial inactivation (i.e., Level III or Level IV)
- Redefining pathogen surrogates for treatment efficacy evaluation to include:
  - *Mycobacterium spp.*

  - Bacterial spore formers

- Reevaluation of the use of bacterial spore formers as ultimate pathogen surrogates, including the determination of which spore formers should be used for which treatment process, and at what level of required inactivation
- Development of specific process approval mechanisms for:
  - Commercial facilities
  - Healthcare facilities
  - Research and development projects
  - Small quantity treatment devices
  - Previously approved technologies
- Refining of criteria specifications and requirements for:
  - Waste residue disposal
  - Operator training
  - Challenge loads
- Redevelopment of specific testing protocols for:
  - State permitting/licensing of the technology
  - Site permitting
  - User verification

Additionally, discussions during STAATT II considered the following:

- Revising list of acceptable biological indicators
- Inclusion of new technologies in the STAATT II report
- Revisions of efficacy testing requirements of treatment technologies
- Release of infectious aerosols/occupational safety
- Use of a regulatory information clearinghouse

The goal of this second STAATT conference was to further explore and refine the issues raised in STAATT I and to reach general consensus on the new issues presented at STAATT II in order to assist state regulators and the commercial manufacturers to meet the challenges presented by medical waste in the next millennium. However, it must be noted that this STAATT guidance document is not a static work but will continue to change as new technologies are introduced, parametric controls are further refined, health care facilities alter their views on the need and methods for waste minimization and regulations are revised as the importance of medical waste is more widely recognized. It may be expected that additional STAATT conferences and revisions of this document will occur in the future.

2

ALTERNATIVE MEDICAL WASTE TECHNOLOGY EFFICACY ASSESSMENT CRITERIA

The establishment of specific criteria that define medical waste treatment efficacy is required to consistently evaluate new or modified medical waste treatment technologies. There are a number of terms that continue to be used in the literature to denote the level of treatment that may be assigned to a medical waste treatment technology (for example, decontaminate, sterilize, disinfect, render harmless, and kill). However these terms are non-descriptive and do not provide any mechanism of measuring the degree of treatment efficiency. It is critical that terms and criteria be established that quantitatively and qualitatively define the level of microbial destruction required of any medical waste treatment process.

As was the case in 1994 when the first STAATT report was made available to state and federal regulators and treatment technology vendors, there are still no federal or national treatment efficacy standards for medical waste treatment technologies. However, while many states have now developed their own treatment efficacy criteria based upon the STAATT guidance document, there is still a need to develop nationally recognized treatment standards and operating protocols which establish the qualitative and quantitative parameters that ensure effective treatment. The American Society for Testing Materials (ASTM) is working on incorporating various components of this report into a standard, and Underwriters Laboratories (UL) has also expressed interest in contributing to the continued development of evaluation criteria. This section provides updated recommended medical waste treatment efficacy assessment criteria and discusses the rationale for its recommendations.

Classification of Present and Emerging Medical Waste Treatment Technologies

To develop approval protocols or criteria for medical waste treatment technologies, it is necessary to classify known or emerging technologies based on their mode of microbial inactivation. Medical waste treatment categories can be represented through the following categories:

- Thermal (moist and dry heat, microwaving, macrowaving, infrared, laser, plasma, pyrolysis, gasification)
- Chemical (chlorine, chlorine derivatives, ozone, enzymes, sodium hydroxide)
- Irradiation (UV, Cobalt 60, electron beam)
- Other microbial inactivation mechanisms designed for specific medical waste categories generated in small volumes (thermal/electrical)

For certain technologies, there may be a combination of modes used to inactivate microorganisms (i.e., chemical/thermal or chemical/irradiation). In addition to the treatment mode, there may be also mechanical grinding introduced prior to, during, and/or at the end of the microbial inactivation process (Note: Grinding, shredding, and/or compaction is not viewed as a treatment method, but is used to assist in treatment efficiency or to render the waste destroyed). The total process by which the medical waste is treated will influence the selection of biological and physical indicators used in the testing and validation processes and will influence the protocols in which they are used.

Sterilization, Disinfection, and Levels of Microbial Inactivation of Medical Waste

Previous to STAATT I in 1994, there was no consensus among the states on the appropriate level of treatment (e.g., degree of microbial inactivation) required of emerging medical waste treatment processes. To properly define microbial inactivation required the establishment of both qualitative and quantitative criteria. From this perspective, standards needed to be established which qualitatively define microbial inactivation (that is, the form and type of microorganisms affected) and which quantify the required level of inactivation. The concepts of sterilization and disinfection continue to be the basis for defining the levels of microbial inactivation of medical waste.

The terms sterilization and disinfection have provided some measure of prescriptive criteria as used for medical instruments and supplies. Sterilization is commonly defined as the complete elimination or destruction of all forms of microbial life, including highly resistant bacterial endospores. Since complete elimination or destruction is difficult to prove, sterilization is usually expressed as a probability function in terms of the number of microorganisms surviving a particular treatment process. This function is usually expressed as a 6 Log_{10} reduction (defined as 6 decade reduction or a one millionth [0.000001] survival probability in a microbial population; i.e., a 99.9999% reduction) of the most resistant microorganisms to the sterilization process in question. Spore suspensions of resistant Bacillus species are often used as biological indicators for determining the efficacy of the sterilization process. *B. stearothermophilus* is used to

indicate the efficacy of thermal inactivation, *B. subtilis* is used for chemical inactivation, and *B. pumilus* is used for irradiation inactivation.

Disinfection can be defined as a procedure which reduces the level of microbial contamination. How disinfection is defined is dependent on the process in which the disinfectant is used, what microorganisms are affected, and what level of microbial inactivation is achieved. In the definition proposed by Spaulding (see Selected Bibliography), disinfectants are labeled as low-, intermediate-, or high-level determined in part on the survivability of microbial groups [that is, bacterial spores (most resistant), mycobacteria, non-lipid or small viruses, fungi, vegetative bacteria, and lipid or medium-sized viruses (least resistant)] after treatment. Low-level disinfectant processes cause the death of: 1) all bacteria except *Mycobacterium tuberculosis* and *M. bovis*, 2) lipid-enveloped and medium-sized viruses (e.g., herpes simplex virus, cytomegalovirus, respiratory syncytial virus, hepatitis B virus, and human immunodeficiency virus), and 3) fungi. Intermediate-level disinfectant processes do not necessarily kill bacterial spores but are effective against tubercle bacillus and fungi. However, intermediate-level disinfectant processes vary in their effectiveness against viruses with small non-lipid viruses (for example, rhinoviruses) being significantly more resistant than medium-sized lipid viruses.

High-level disinfectant processes cause the death of all microbial life, except for high numbers of bacterial spores. Sporicidal capacity is an essential property of high-level disinfection, although the amount of sporicidal activity is not quantified in any definition.

Initial Classification System for Microbial Inactivation - 1994

It was agreed during the New Orleans meeting for STAATT I that there was a need to establish a separate classification system which would specifically denote levels of microbial inactivation required of medical waste treatment. This classification system would quantitatively and qualitatively define the measure of required performance. To aid in the establishment of a separate classification system, the following categories of microbial inactivation were offered and discussed:

Level I	Inactivation of vegetative bacteria, fungi, and lipophilic virus
Level II	Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria
Level III	Inactivation of vegetative bacteria, fungi, all viruses, mycobacteria, and *B. stearothermophilus* spores at 10^4 or greater; or *B. subtilis* spores at 10^4 or greater with chemical treatment
Level IV	Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria, and *B. stearothermophilus* spores at 10^6 or greater

In the New Orleans meeting (STAATT I, December, 1992), most participants generally favored Level III criteria for emerging medical waste treatment technologies. Although there was considerable discussion at that meeting, no consensus had been reached on the qualitative and quantitative aspects of the Level II and III definitions and the conditions to be applied, if any, for relaxation of the Level III requirement to Level II.

A primary objective of the Atlanta meeting (STAATT I, February 1993) was to specifically define the qualitative and quantitative aspects of the microbial inactivation definitions and to assign their application. To meet this objective, discussions centered on:

- Defining microbial inactivation levels by representative microbial groups and by the amount of microbial inactivation required for each
- Assigning representative pathogen surrogates to be used in the treatment efficacy evaluation processes
- Assigning inactivation levels required of a medical waste treatment technology

To assist the participants in further defining Levels I-IV, a summary was provided at the Atlanta meeting of the results of EPA sponsored research on the efficacy of emerging medical waste treatment technologies. Summarized were the treatment technologies evaluated, the surrogate organisms selected for testing and rationale for their selection, and in general, the results obtained from this research project. At that time, it was stated that the research material presented was not yet available for review since this material was to serve as an appendix to the U.S. EPA's "Final Report to Congress" when finalized.

Note: A "Final Report to Congress" on the Medical Waste Tracking Act of 1988 has never materialized. However, the EPA sponsored treatment efficacy research reports referenced above are available and have proven to be useful in the development of STAATT I and STAATT II. (See Selected Bibliography.)

Of particular interest to the participants was the availability of documentation that would support the use of an ultimate pathogen surrogate (i.e., *Bacillus stearothermophilus* spores) that could be used to avoid the testing of representative pathogen surrogates from each of the microbial groups listed in the definitions above. As part of the EPA sponsored study, comparative tests with vegetative bacteria, bacterial spores, fungal spores, and mycobacteria demonstrated that *B. stearothermophilus* and *B. subtilis* spores could be used to represent vegetative bacteria, fungi, and mycobacteria in evaluating both chemical and thermal (wet and dry heat) treatment systems.

No comparative testing, however, had been conducted with viruses or parasites. Without this supporting documentation for viruses and parasites, the participants could

not recommend that *B. stearothermophilus* or *B. subtilis* be designated as an ultimate pathogen surrogate for medical waste treatment efficacy testing. As such, the STAATT I participants took the position to recommend that pathogen surrogates representing vegetative bacteria, fungi, parasites, viruses, mycobacteria, and bacterial spores be used to demonstrate treatment efficacy. To determine if *B. stearothermophilus* and *B. subtilis* spores could be used in the future as pathogen surrogates representing all microbial groups, the participants recommended at that time that further research be conducted to evaluate their relative resistance to representative parasitic agents (such as *Giardia* and *Cryptosporidium*) and viral agents (such as Polio 2, MS-2).

In the categories depicted as Level I-IV above, each Level represents a hierarchy of increasing treatment resistance where treatment resistance is defined by the type of microorganism requiring inactivation and/or the amount of inactivation required for that type of microorganism. The definition of these categories requires that all groups of pathogen surrogate microorganisms recommended for testing be included in the definition. To be consistent with the participant's recommendation that a representative microorganism be tested from each microbial group, the definitions of Levels II-IV were modified to include "parasites." Additionally, it was suggested that "all viruses" was too inclusive and it was recommended that "all viruses" be modified to "lipophilic/hydrophilic viruses." These changes were reflected in the definition for the "Levels of Microbial Inactivation" as presented in Table 2-1.

It should be noted that the inactivation levels defined in Table 2-1 are not to be construed as having any relationship with treatment efficacy requirements for microorganisms in Biosafety Levels I-IV as defined within guidelines set by the Centers for Disease Control/National Institutes of Health in "Biosafety in Microbiological and Biomedical Laboratories" (3rd edition, May 1993).

Table 2-1
Levels of Microbial Inactivation (STAATT I)

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

Inactivation of spores from both *B. stearothermophilus* and *B. subtilis* is also defined in Levels III and IV. It was questioned whether these microorganisms were the most chemically or thermally resistant biological indicators. From information provided, the use of these microorganisms as the most resistant indicators to thermal and chemical agents is supported in the literature.

To avoid assigning a specific bacterial species for each specific treatment process, documentation was sought that would support the use of spores from just one bacterial species for both chemical and thermal treatment processes. In the EPA sponsored studies comparing *B. stearothermophilus* and *B. subtilis* resistance to hypochlorite (1000 ppm available free chlorine) and glutaraldehyde (3000 ppm, 2% alkaline glutaraldehyde), the resistance of spores from both was comparable. Data also supported that *B. stearothermophilus* spores were slightly more resistant to dry heat than *B. subtilis* var. niger spores (the *B. subtilis* variety traditionally used to determine dry heat resistance). This data indicates that B. *stearothermophilus* can be used as the sole spore indicator for chemical treatment processes and as the sole spore indicator for both dry and wet heat thermal processes.

B. stearothermophilus spores, however, are more resistant to wet heat than spores *from B. subtilis* . Debate centered on whether spores from either species could be used interchangeably for wet or dry heat thermal processes even though *B. stearothermophilus* spores are more resistant to wet heat. It was argued that the use of spore inactivation in the definition serves two functions: (1) to demonstrate that bacterial spore formers (originating primarily from laboratory wastes) can be inactivated and (2) to provide a margin of safety beyond the inactivation of vegetative bacteria, fungi, viruses, parasites, and mycobacteria.

From the first perspective, both *B. stearothermophilus* and *B. subtilis* spores are used as indicators of medical product sterility because of their documented resistance to heat and chemicals. Inactivation of either of these highly resistant bacteria spores serves to demonstrate that any spores found in medical waste will also be inactivated. From the second perspective, *B. subtilis* and *B. stearothermophilus* spores both display significantly more heat resistance than the microorganisms in the aforementioned microbial groups. The demonstration that highly resistant spores from either of these Bacillus species can be effectively destroyed ensures a margin of safety from the variables inherent in the treatment of medical waste (i.e., waste packaging, waste composition, waste density, and factors influencing the homogeneity of the treatment process).

On the basis of these arguments presented above, the participants recommended that either *B. stearothermophilus* or *B. subtilis* spores be used as biological indicators for chemical or thermal treatment processes. The question arose, however, as to whether a higher level of inactivation would be required when using *B. subtilis* for wet heat treatment processes. It was argued that *B. stearothermophilus* and *B. subtilis* spores both have a documented high degree of thermal resistance. As such, higher inactivation levels required of *B. subtilis* spores for wet heat treatment processes were considered unnecessary to further demonstrate effective spore inactivation or an expanded margin of safety. In addition, it was argued that assigning different threshold inactivation levels for each defined biological indicator would set a bad precedent and lead to an overly and unnecessarily complex definition. The revision to allow the use of either *B. stearothermophilus* and *B. subtilis* spores as biological indicators for chemical or thermal treatment processes is reflected in the recommended definition for the "Levels of Microbial Inactivation" as presented in Table 2-1.

The use of *B. stearothermophilus* or *B. subtilis* spores for demonstrating medical waste treatment efficacy by irradiation processes was also recommended. While *B. pumilus* spores are used as the standard biological indicator to demonstrate irradiation treatment efficacy in the sterilization of medical products, they are not as resistant to irradiation as the enteroviruses or the vegetative bacterium *Dinococcus radiodurans*. Therefore, the use of an enterovirus (for example, Polio 2 or Polio 3) or *D. radiodurans* can provide a more stringent measure of treatment efficacy than *B. pumilus* spores. However, despite these facts, inactivation of *B. stearothermophilus* or *B. subtilis* spores could still be used to adequately demonstrate that any spores found in medical waste will also be inactivated.

Specific levels of inactivation are required of any adopted definition to quantitatively define the measure of required performance of a medical waste treatment technology. The definitions proposed by the participants stated that inactivation was required of "vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria". Although implied but not specifically stated, this definition required complete inactivation of the representative microorganisms tested in each of the microbial groups listed. Since complete inactivation is impossible to prove, it can be

expressed as a probability function in terms of the number of microorganisms surviving a particular treatment process. In defining sterilization, this function is usually expressed as a 6 Log_{10} reduction. A 6 Log_{10} reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (in other words, a 99.9999% reduction). Using this definition as a basis for quantifying complete inactivation, the recommendation was made that 6 Log_{10} reduction be required of the representative microorganisms tested in each of the microbial groups listed (with the exception of *B. stearothermophilus* or *B. subtilis* spores), as noted in Table 2-1, "Levels of Microbial Inactivation."

For inactivation levels required of *B. stearothermophilus* or *B. subtilis* spores, the original definition stated that inactivation was required at "10^4 or greater" (i.e., 4 Log_{10} reduction or greater). It was questioned whether this level should remain as stated in the definition or modified to be less or more stringent. In the EPA sponsored studies it was demonstrated that of the medical waste treatment technologies studied, all could meet at least a 4 Log_{10} reduction of *B. stearothermophilus* or *B. subtilis* spores. The participants supported the level as defined in the original definition. Language however, was modified to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction. A 4 Log_{10} reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction). The participants also revised the Level IV definition to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction and are reflected in Table 2-1.

Recommendations made by the participants for establishing a quantitative and qualitative definition for the "Levels of Microbial Inactivation" were incorporated into Categories I-IV of Table 2-1 and are summarized as follows:

- Pathogen surrogates representing vegetative bacteria, fungi, parasites, lipophilic/ hydrophilic viruses, mycobacteria, and bacterial spores should be used to demonstrate treatment efficacy

- Either *B. stearothermophilus* or *B. subtilis* spores should be used as biological indicators for chemical or thermal treatment or irradiation processes

- A 6 Log_{10} reduction should be required of the representative microorganisms tested in each of the microbial groups listed (with the exception of *B. stearothermophilus* or *B. subtilis* spores)

- A 4 Log_{10} reduction level should be required of *B. subtilis* or *B. stearothermophilus* spores

Having quantitatively and qualitatively established a definition for the "Levels of Microbial Inactivation", arguments were presented and discussed to determine the

position of the participants on which category would serve as the benchmark criteria for medical waste treatment efficacy. Debate centered on the recommendation of Level II or Level III criteria.

Arguments for recommending Level II criteria were as follows:

- Medical waste does not contain significant differences in amount and type of pathogens as household waste
- Level II criteria provides a sufficient degree of microbial inactivation
- Level III criteria may conflict with lesser inactivation criteria already defined by the state
- Level III or IV criteria can be applied, if necessary, to those medical waste streams requiring an additional margin of safety

Arguments for recommending Level III treatment criteria were:

- Level III treatment criteria serves as a margin of safety from the variables inherent in the treatment of medical waste (including waste packaging, waste composition, waste density, and factors influencing the homogeneity of the treatment process)
- Segregation of some medical waste categories (that is, laboratory cultures) requiring Level III treatment would be impractical if Level II criteria were in effect
- The medical waste treatment equipment industry already achieves Level III treatment criteria
- Level II or Level IV treatment criteria may still be allowed depending on the technology application or waste type processed

It was the consensus (not the unanimous opinion) of the STAATT I participants that Level III criteria be required of all emerging medical waste technologies. The participants took the position that Level III treatment criteria were to be established as a benchmark and as such, were applicable to all medical waste treatment devices.

The participants rejected the allowance for exception to Level II standards for those technologies that could be termed "counter top" devices designed for a specific medical waste category. Relaxation from Level III to Level II criteria was not considered warranted on the basis of the following equipment characteristics:

- Inability to inactivate spores
- Designation as a small quantity treatment device

- Designation for treating minimally contaminated medical waste categories
- Difficulty in demonstrating microbial inactivation through designated protocols (such as a needle thermal-destruction device)

The participants realized that there might be circumstances under which a state may allow relaxation of the Level III requirement. These exceptions would need to be made on a case-by-case basis, would require the equipment manufacturer to provide rationale for relaxation, and would require adequate supporting documentation to substantiate that rationale.

The STAATT II meeting participants continue to recommend at a minimum Level III inactivation parameters for all medical waste treatment technologies.

As was the case in 1994, 1998 STAATT II participants were of the opinion that the waste generated by clinical microbiological laboratories constitutes the most dangerous portion of the medical waste stream. Therefore, the participants recommended that all microbiological waste be treated on-site by either conventional or alternative technologies. Even if facilities contract to have medical waste hauled from their laboratories for treatment and disposal, it was the advice of all present that microbiological waste not be included with untreated waste. Microbiological products should be treated on-site and then discarded with the routine non-medical solid waste to be handled by solid waste haulers for eventual disposal in a sanitary landfill.

These recommendations are in line with the guidelines set by the Centers for Disease Control in "Biosafety in Microbiological and Biomedical Laboratories" (1993). Similar recommendations may be forthcoming from the CDC Hospital Environmental Guidelines currently in revisions for the Hospitals Infection Control Practices Advisory Committee (HICPAC).

Updated Representative Biological Indicators

STAATT I provided a table of pathogen surrogates representing vegetative bacteria, fungi, parasites, viruses, mycobacteria, and bacterial spores that was considered necessary to define and facilitate any state approval process. In the absence of an ultimate pathogen surrogate to represent all defined microbial groups, the selection criteria defining surrogate selection still includes that any surrogate recommended meet the following criteria:

- Ineffective in healthy individuals
- Easily obtainable
- A registered strain, as available

- Easily cultured and maintained
- Compliant with quality control requirements

Microorganism strains obtained from the American Type Culture Collection (ATCC) and methods prescribed by the Association of Official Analytical Chemists (AOAC) assist in fulfilling these recommendations by: 1) providing traceable and pure cultures of known characteristics and concentration, and 2) providing recognized culturing protocols and detailed sampling and testing protocols.

Provided in Table 2-2 are the minimum biological indicators recommended by the STAATT II participants for testing microbial inactivation efficacy in medical waste treatment processes. The selection of these representatives was based on; (1) each microorganism meeting, wherever possible, the criteria described above and (2) each providing an equivalent biological challenge or greater to that associated with microorganisms found in medical waste.

Biological indicators selected to provide documentation of relative resistance to an inactivating agent should be chosen after evaluation of the treatment process as it relates to the conditions used during comparative resistance research studies described in the literature. Literature studies support the assertion that the degree of relative resistance of a microorganism to an inactivating agent can be dependent on various factors (for example, pH, temperature). Conditions used in literature studies that demonstrate a relatively high degree of resistance of a particular microorganism may be significantly different to the conditions found within the treatment process. A comparison of the conditions used in the literature to those used in the treatment process should be made to determine if relative microbial resistance can be altered (i.e., lowered) as a result of treatment process conditions.

It has become apparent in the tests performed with many different technologies as required by state regulatory agencies, that the use of additional biological indicators provides no additional safeguards to public health and safety by further insuring the efficient operations of treatment systems. However, they do significantly add to costs of efficacy tests conducted by independent laboratories funded by the manufacturers. It was argued in STAATT II that the use of bacterial spores as the sole biological indicator provides a margin of safety beyond the inactivation of vegetative bacteria, fungi, viruses, parasites, and mycobacteria. Therefore, a reduction in the number of biological indicator organisms used for efficacy testing should now be considered.

As an example, selection and use of the parasite *Giardia* has proven to be quite difficult to evaluate in medical waste treatment systems. First, growth of the organism to a concentration that would meet the Level III inactivation criteria is not possible. Second, there are only a limited number of researchers in the U.S. that have the expertise to work with *Giardia*. Third, testing for this organism is most practical using a laboratory

scale model of the medical waste treatment technology. As will be discussed later, this method of testing as the only source of efficacy data may not be acceptable for approval at the state level.

After considerable discussion, the STAATT II participants recommended at a minimum a 6 Log_{10} reduction in the concentration of *Mycobacteria bovis* BCG, *M. phlei* or other species of mycobacteria and a 4 Log_{10} reduction in the level of *Bacillus* spores. The participants believed that the factors which contributed to the initial recommendations to achieve these Level III inactivation parameters are still valid today. Additionally, these two microorganisms have been historically viewed as very resistant to inactivation by thermal and chemical means.

As with STAATT I in 1994, it is emphasized that although the microorganisms selected represent pathogen surrogates, all microorganisms have the potential to be pathogenic. As such, it is recommend that all testing be conducted using good laboratory techniques. Efficacy testing should be conducted only by qualified laboratory personnel.

Table 2-2
Recommended Biological Indicators (STAATT II)

Mycobacteria	*Mycobacterium phlei* *Mycobacterium bovis* (BCG) (ATCC 35743)
Bacterial Spores	*Bacillus stearothermophilus* (ATCC 7953) *Bacillus subtilis* (ATCC 19659)

Specific criteria for the selection of the most appropriate of these microorganisms are as follows:

Mycobacteria

Mycobacterium phlei has a demonstrated measure of disinfectant resistance, is a rapid grower and is pigmented for easy identification. *M. bovis* (BCG) is used in the AOAC Tuberculocidal Method and is analogous to *M. tuberculosis* in that it is in the same group or complex. Individuals exposed to *M. bovis* (BCG, ATCC strain) may skin test convert although no actual infectivity or disease occurs. Risk of exposure would come from those mechanisms that grind the waste.

Bacterial Spores

Both *B. stearothermophilus* and *B. subtilis* spores are commonly used as biological indicators for both thermal and chemical resistance. *B. stearothermophilus* spores exhibit more thermal and chemical resistance than spores from *B. subtilis* .

Note: These are the minimum recommendations from STAATT II. While it is hoped that states might consider utilizing this reduced list of microorganisms, individual states are still able to apply more stringent requirements. It is for this reason the long list of biological indicators and their associated ATCC accession numbers are included in a separate table in the appendix. Manufacturers are free to include other indicators, such as bacteria, fungi, and viruses. Until a national efficacy standard is developed, manufacturers should still contact the states where they are seeking approval to determine what the recommended biological indicators for efficacy testing are.

Quantification of Microbial Inactivation

Establishing the mechanisms to quantify the level of microbial inactivation continues to be essential in developing the format and requirements of the guidance protocols. As presented and discussed, microbial inactivation ("kill") efficacy is equated to "Log_{10} kill" which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is translated into the following formula:

Log_{10} kill = Log_{10}(cfu/g Introduced) -Log_{10}(cfu/g Recovered),

where:

"Log_{10} kill" is equivalent to the term Log_{10} reduction.

"Introduced" is the number of viable test microorganisms introduced into the treatment unit.

"Recovered " is the number of viable test microorganisms recovered after treatment.

"cfu/g" are colony forming units per gram of waste solids.

A Log_{10} kill of 6 or greater is equivalent or less than a one millionth [0.000001] survival probability in a microbial population or a 99.9999% reduction or greater of that population.

Using the definition recommended by the STAATT I participants as shown in Table 2-1, a Log_{10} kill of 6 (e.g., 6 Log_{10} reduction) is required of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria and a Log_{10} kill of 4 (e.g., 4 Log_{10} reduction) is required of *B. stearothermophilus* or *B. subtilis* spores. Employing the above equation to quantify microbial inactivation will require the consideration of the methods of biological indicator introduction and recovery. For those treatment processes that can maintain the integrity of the carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, commercially available biological indicators of the required strain and concentration can be easily placed, recovered, and cultured to demonstrate treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator. For example if an ampoule containing 1×10^4 *B. stearothermophilus* spores was treated, retrieved, and cultured, resultant no growth would demonstrate a 4 Log_{10} reduction.

For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator carrier, quantitative measurement of treatment efficacy requires a two step approach. The purpose of the first step is to account for the reduction of microorganisms due to equipment design (such as dilution of indicator organisms or physical entrapment).

This first step, the "Control", is typically performed using microbial cultures (i.e., liquid suspensions) of a predetermined concentration that is necessary to ensure a sufficient microbial recovery at the end of this step. The microbial suspension is added to a standardized surrogate medical waste load that is processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals). Standard loads may vary depending the various treatment challenges (i.e., high moisture content, high organic load, high density) required of the equipment. After processing, waste samples are collected and washed to recover the biological indicator organisms in the sample. Recovered microorganism suspensions are plated to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the microbial inactivation agent. The required number of recovered viable indicator microorganisms from the "Control" must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction as defined in Level III (i.e., a 6 Log_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for spores). See Appendix A (Section C3) and Appendix B for a detailed process description. This step can be defined by the following equation:

$$Log_{10}RC = Log_{10}IC - Log_{10}NR,$$

where: $Log_{10}RC > 6$ for vegetative microorganisms and > 4 for bacterial spores and

where: $Log_{10}RC$ is the number of viable "Control" microorganisms (in colony forming units per ram of waste solids) recovered in the non-treated processed waste residue.

$Log_{10}IC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit.

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered after processing.

Rearranging the equation above enables the calculation of microbial loss due to dilution, physical manipulation, or residue adhesion during the treatment process. $Log_{10}NR$ represents an accountability factor for microbial loss and is defined by the following equation:

$$Log_{10}NR = Log_{10}IC - Log_{10}RC.$$

The second step ("Test") is to operate the treatment unit as in the "Control" run with the selected biological indicators, but with the addition of the microbial inactivation agent. After processing, waste samples are collected and washed as in the "Control" to recover any viable biological indicator organisms in the sample. From data collected from the "Test" and "Control", the level of microbial inactivation (i.e., "Log_{10} kill") can be calculated by employing the following equation:

$$Log_{10}\ kill = Log_{10}IT - Log_{10}NR - Log_{10}RT,$$

where: Log_{10} kill is equivalent to the term Log_{10} reduction;

$Log_{10}IT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit.

$$Log_{10}IT = Log_{10}IC;$$

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered after processing;

$Log_{10}RT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.

Appendix B (in the Calculations section) serves to illustrate the application of the equations presented above.

Formulas used in the discussion above for the quantification of microbial inactivation were modified from those used by Illinois EPA in their final (June 1993) regulations entitled "Potentially Infectious Medical Wastes" (see Selected Bibliography).

After discussion on the use and application of the formulas and calculations presented above, consensus by the participants was unanimous on recommending the use of the formulas and methods of calculation in the enumeration of medical waste treatment efficacy.

3

ALTERNATE MEDICAL WASTE TECHNOLOGY APPROVAL PROCESS

State approval of an emerging medical waste treatment technology is necessary to ensure that the technology can effectively and safely treat medical waste. From discussions, the completed approval process can be viewed as fulfilling, where applicable, the following two components:

- Approval of the technology by the state to ensure that the technology is effective in safely inactivating microorganisms to specified criteria
- Site approval to verify that the sited equipment meets approved specifications and treatment efficacy requirements under actual operating conditions

Each of these requires that information be supplied to the state which demonstrates that the treatment technology is effectively treating medical waste by established criteria and that the process is environmentally sound and occupationally safe. Information necessary for proper review of medical waste treatment technologies is provided for each component described below.

Biological Inactivation Efficacy: Establishment of Protocols

Methodology employed to determine treatment efficacy of the technology will, by necessity, need to be developed by the equipment manufacturer to assure the protocols are congruent with the treatment method. Protocols developed for *efficacy testing should incorporate recognized standard procedures such as those in Test Methods for Evaluating Solid Waste, Physical/Chemical Methods* and *Standard Methods for the Examination of Water and Waste Water* (see Selected Bibliography).

In establishing testing criteria to evaluate treatment efficacy, the composition of the waste load(s) tested is critically important. Dependent on the mechanism of microbial inactivation, treatment efficacy may vary with the waste load composition (i.e., organic content, density, moisture or liquid content). Although the participants recognized that waste composition may considerably affect treatment efficacy results, establishing specific requirements for challenge loads for all existing, pending, and future treatment

technologies is not practical or necessarily all inclusive. The participants recommended that the equipment manufacturer prescribe those types of medical wastes that present the most challenge to treatment effectiveness of the equipment and present protocols that adequately evaluate treatment efficacy under normal operating conditions. Upon submittal for evaluation by the state, the manufacturer's prescribed waste types and testing protocols could be accepted or modified at the discretion of the reviewing agency.

Dependent on the treatment process and treatment efficacy protocols used, other factors may also influence the results of the treatment efficacy evaluation. As such, the participants could not define specific treatment efficacy protocols, but recommended that protocols evaluating medical waste treatment systems specifically delineate or incorporate the following:

- Waste compositions that typify actual waste to be processed and provide the worse case scenario for the treatment process (i.e., high organic load content for chemical systems)
- Perform tests on actual treatment equipment versus bench top scale models of the actual systems
- Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume)
- Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process
- Assurances of inoculum traceability, purity, viability and concentration
- Dilution and neutralization methods that do not affect microorganism viability
- Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples per test, number of colony forming units per plate)
- Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times)

Physical or aesthetic characteristics may also predicate the limitations applied or the conditions of the equipment's use. If certain medical waste categories are excluded from the treatment process, the state should address for the manufacturer (vendor) and the user of the equipment the waste segregation parameters that will be employed to prohibit the waste from treatment and the mechanisms of treatment/disposal to be utilized for these excluded wastes.

It was recommended by the participants that efficacy testing protocols and results of the evaluation conducted, including original data, be included for evaluation by the state agency reviewing the application for treatment technology approval. The methodologies and protocols developed are especially critical for state evaluation of medical waste treatment processes that pulverize, grind, or shred the waste during the treatment process and do not allow intact retrieval of the biological test indicator. The complexity of these protocols is illustrated in Appendix B, "Example: Treatment Efficacy Protocol for a Grinder/Chemical Medical Waste Inactivation Process."

To establish proper protocols that incorporate the recommended criteria above and meet any applicable recognized testing standards will, in most likelihood, require the equipment manufacturer to seek assistance from an independent laboratory. The participants recommended that to ensure the required quality control and facilitate state review of the treatment process, the qualified laboratory selected should:

- Be experienced in microbiological testing techniques and be familiar with required sampling and testing protocols
- Be an accredited laboratory or have experience with product registration through Food and Drug Administration (FDA) or EPA Office of Pesticide Programs
- Be equipped to meet FDA "Good Laboratory Practices" requirements

Alternate Medical Waste Treatment Technology Approval

As a first step in the review process, information is required of the manufacturer to provide the state with the information it needs to properly assess the treatment technology proposed for approval. The state's use of a comprehensive information request form is essential in obtaining relevant information and in acquainting the manufacturer with the requirements and the responsibilities inherent in the review process. To meet these objectives, the form should perform the following tasks:

- Delineate state responsibilities and permitting requirements
- Delineate manufacturer responsibilities and registration requirements
- Provide a detailed description of the medical waste treatment equipment to be tested including manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, temperatures, pressure, chemical concentrations, irradiation doses, feed rates, and waste load composition
- Provide documentation demonstrating that the treatment method meets microbial inactivation criteria and required testing protocols, including a detailed description

of the test procedures and calculations used in fulfilling designated performance standards verifying treatment efficacy, of user verification methodology, and of microbial culturing protocols which ensure traceability, purity and concentration

- Provide documentation of applicable emission controls for suspected emissions
- Provide documentation for occupational safety and health assurance

In additional to fulfilling environmental and occupational safety requirements, all treatment technologies must meet Level III efficacy criteria. Demonstration that these criteria are met is the responsibility of the equipment manufacturer. In meeting these requirements the manufacturer must:

- Demonstrate that all required pathogen surrogates and resistant bacterial endospores (as recommended in Table 2-2) are inactivated to Level III criteria under all required challenge waste load compositions
- Develop and demonstrate that site approval and user verification testing protocols are workable and valid
- Demonstrate, where technically practical, the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment

To assist in presenting the recommendations for treatment efficacy review, an approval process guideline is presented in Appendix A.

Parametric Monitoring and Control

Parametric monitoring of a medical waste treatment process can provide real-tine data acquisition for assessing treatment efficiency. However, correlation of the data acquired from the parametric monitoring device(s) with that of biological indicator studies is essential if parametric monitoring is to supplement or replace biological indicator monitoring. This demonstration is the responsibility of the manufacturer (vendor). To verify that a proper correlation has been established between the parametric monitoring device and biological indicator inactivation, the manufacturer (vendor) must demonstrate that parametric monitoring is:

- Correlated with biological indicator inactivation through documented efficacy studies linking microbial inactivation with the parameter(s) being monitored
- Accurately monitoring the treatment agent and/or treatment conditions, as applicable (i.e., provide the limiting conditions that influence accurate monitoring

- Appropriate for the conditions that exist under operational circumstances

Demonstration of the above components may allow the use of parametric monitoring for auditing treatment conditions or alerting the equipment's operator of equipment malfunction or abnormal behavior. However, the use of parametric monitoring to substitute or replace biological indicator inactivation must require the device to additionally:

- 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 conditions are not appropriate
- Be calibrated periodically as specified by the monitoring device's manufacturer
- Provide a tamper-proof recording of all monitored parameters

The participants recommended that parametric monitoring could substitute or replace biological indicator monitoring provided that all of the above conditions were achieved.

Alternate Medical Waste Treatment Technology Site Approval

The purpose of the site approval process is to ensure that the treatment equipment sited is the same equipment and process approved by the state. Site approval may also require obtaining other state permits (i.e., solid waste treatment/disposal permits; emissions and discharge permits) in addition to those required under state medical waste regulations. Treatment efficacy must also be demonstrated under actual operating conditions. However, the rigor of the biological indicator testing would be less than the testing required for technology approval, although tests conducted would be required to reflect the waste load compositions of waste treated. Effectiveness and reliability of the real-time treatment monitoring systems must also be demonstrated to receive site approval. Additionally, agency review is necessitated to verify proper and safe operations, verify disposal of waste residues, and verify operator training.

Specifically, to fulfill treatment efficacy and information requirements recommended for site approval, the equipment user must:

- Demonstrate that required resistant bacterial endospores (as recommended in Table 2-2) are inactivated to Level III criteria under typical waste load and challenge compositions
- Verify that user verification protocols adequately demonstrate treatment effectiveness

- Verify the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment (i.e., correlation of biological indicator inactivation with time and temperature via thermocouple monitoring)
- Document the following in a written operation plan:
  - The names or positions of the equipment operators
  - The waste types or categories to be treated
  - Waste segregation procedures required
  - Wastes types prohibited for treatment
  - Equipment operation parameters
  - Treatment efficacy monitoring procedures
  - Contingency waste disposal plans
  - Personal protective equipment requirements
  - Emergency response plans
  - Operator training requirements
- Provide the following for state review:
  - Equipment model number and serial number
  - Equipment specification and operations manual
  - User's written plan
  - Certification documentation of operator training

The state may want to visit the site of proposed operation to validate operations or site approval may be granted through the submittal of the requested information and documents. As a condition of site approval, the state should affirm its rights to inspect the facility and to revoke site approval if health and safety violations are discovered, if permit conditions are not being fulfilled, or if the facility is not adhering to its written plan.

U.S. EPA Pesticide Use Registration

The use of a chemical agent in any microbial inactivation process may involve pesticide registration with the U.S. EPA Pesticide Registration Office under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The U.S. EPA Pesticide Registration Office's involvement in the regulatory process is dependent on advertising claims made by the medical waste treatment equipment's manufacturer (vendor). If claims are made that specify a level of treatment inactivation by term (i.e., kills pathogens, disinfects), registration with the U.S. EPA Pesticide Registration Office is required.

FIFRA now requires the chemical agent to be approved specifically for the medical waste treatment technology in which it is being used. Additional information can be obtained by contacting the Ombudsman for the Antimicrobials Division of the EPA at (703) 308-6214.