

# **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**

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# REPORT SUMMARY

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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.

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## 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

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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

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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

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<b>1 INTRODUCTION.....</b>	<b>1-1</b>
<b>2 ALTERNATIVE MEDICAL WASTE TECHNOLOGY EFFICACY ASSESSMENT CRITERIA .....</b>	<b>2-1</b>
Classification of Present and Emerging Medical Waste Treatment Technologies.....	2-1
Sterilization, Disinfection, and Levels of Microbial Inactivation of Medical Waste .....	2-2
Initial Classification System for Microbial Inactivation - 1994 .....	2-3
Updated Representative Biological Indicators .....	2-10
Quantification of Microbial Inactivation .....	2-13
<b>3 ALTERNATE MEDICAL WASTE TECHNOLOGY APPROVAL PROCESS.....</b>	<b>3-1</b>
Biological Inactivation Efficacy: Establishment of Protocols.....	3-1
Alternate Medical Waste Treatment Technology Approval .....	3-3
Parametric Monitoring and Control.....	3-4
Alternate Medical Waste Treatment Technology Site Approval .....	3-5
U.S. EPA Pesticide Use Registration .....	3-7
<b>4 PERMITTING AND STATE AUTHORIZATION ISSUES.....</b>	<b>4-1</b>
User Verification: Biological Inactivation Efficacy Monitoring .....	4-1
Commercial Versus On-Site Facilities .....	4-1
Previously Approved Technologies .....	4-2
Small Medical Waste Treatment Devices .....	4-4
Waste Residue Disposal .....	4-4
Operator training .....	4-6
Equipment Operations Plan.....	4-6
Emergency and Contingency Response Plan.....	4-7
<b>5 RESEARCH AND DEVELOPMENT.....</b>	<b>5-1</b>

---

<b>6 RECOMMENDATIONS FOR FUTURE ACTIVITIES.....</b>	<b>6-1</b>
<b>7 SELECTED BIBLIOGRAPHY .....</b>	<b>7-1</b>
<b>8 GLOSSARY.....</b>	<b>8-1</b>
<b>A STATE GUIDELINES FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES .....</b>	<b>A-1</b>
Preface.....	A-1
A. Definition of Microbial Inactivation.....	A-1
B. Representative of Biological Indicators .....	A-1
C. Quantification of Microbial Inactivation.....	A-2
D. Efficacy Testing Protocols.....	A-5
E. Technology Approval Process.....	A-5
F. Site Approval Process .....	A-7
G. User Verification .....	A-8
H. Small Medical Waste Treatment Devices.....	A-9
I. Previously Approved Technologies .....	A-10
J. Waste Residue Disposal.....	A-11
K. Operator Training.....	A-12
L. Research and Development .....	A-13
<b>B TREATMENT EFFICACY TESTING PROTOCOL FOR A GRINDER/CHEMICAL MEDICAL WASTE INACTIVATION PROCESS.....</b>	<b>B-1</b>
I. Materials .....	B-1
II. Protocols .....	B-1
A. Control Run.....	B-1
B. Test Run .....	B-3
III. Calculations.....	B-4
<b>C EXISTING MEDICAL WASTE TREATMENT TECHNOLOGIES.....</b>	<b>C-1</b>
<b>D PARTICIPANTS STAATT II .....</b>	<b>D-1</b>

# LIST OF TABLES

---

Table 2-1 Levels of Microbial Inactivation (STAATT I).....	2-6
Table 2-2 Recommended Biological Indicators (STAATT II).....	2-12



# EXECUTIVE SUMMARY—STAATT I (APRIL 1994)

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## 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 commonality 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<sub>10</sub> reduction or greater; and inactivation of *Bacillus stearothermophilus* spores or *Bacillus subtilis* spores at a 4 Log<sub>10</sub> reduction or greater.

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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<sub>10</sub> 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

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- 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)

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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;

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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

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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<sub>10</sub> reduction in the concentration of *Mycobacteria*, e.g., *M. bovis* BCG, *M. phlei* or other species of mycobacteria and a 4 Log<sub>10</sub> 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 metal 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

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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

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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

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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**

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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<sub>10</sub> 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 <i>B. stearothermophilus</i> spores at $10^4$ or greater; or <i>B. subtilis</i> spores at $10^4$ or greater with chemical treatment |
| Level IV  | Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria, and <i>B. stearothermophilus</i> 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)**

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Level I	Inactivation of vegetative bacteria, fungi, and lipophilic viruses at a 6 Log <sub>10</sub> reduction or greater
Level II	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log <sub>10</sub> reduction or greater
Level III	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log <sub>10</sub> reduction or greater; and inactivation of <i>B. stearothermophilus</i> spores or <i>B. subtilis</i> spores at a 4 Log <sub>10</sub> reduction or greater
Level IV	Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, mycobacteria, and <i>B. stearothermophilus</i> spores a 6 Log <sub>10</sub> reduction or greater

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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<sub>10</sub> reduction. A 6 Log<sub>10</sub> 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<sub>10</sub> 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<sup>4</sup> or greater" (i.e., 4 Log<sub>10</sub> 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<sub>10</sub> 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<sup>4</sup> or greater" with "4 Log<sub>10</sub> reduction or greater" to be consistent with the use of the definition of Log<sub>10</sub> reduction. A 4 Log<sub>10</sub> 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<sup>4</sup> or greater" with "4 Log<sub>10</sub> reduction or greater" to be consistent with the use of the definition of Log<sub>10</sub> 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<sub>10</sub> 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<sub>10</sub> 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<sub>10</sub> reduction in the concentration of *Mycobacteria bovis* BCG, *M. phlei* or other species of mycobacteria and a 4 Log<sub>10</sub> 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)**

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Mycobacteria	<i>Mycobacterium phlei</i> <i>Mycobacterium bovis</i> (BCG) (ATCC 35743)
Bacterial Spores	<i>Bacillus stearothermophilus</i> (ATCC 7953) <i>Bacillus subtilis</i> (ATCC 19659)

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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<sub>10</sub> 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:

$$\text{Log}_{10} \text{ kill} = \text{Log}_{10}(\text{cfu/g Introduced}) - \text{Log}_{10}(\text{cfu/g Recovered}),$$

where:

“Log<sub>10</sub> kill” is equivalent to the term Log<sub>10</sub> 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<sub>10</sub> 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<sub>10</sub> kill of 6 (e.g., 6 Log<sub>10</sub> reduction) is required of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria and a Log<sub>10</sub> kill of 4 (e.g., 4 Log<sub>10</sub> 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<sup>4</sup> *B. stearothermophilus* spores was treated, retrieved, and cultured, resultant no growth would demonstrate a 4 Log<sub>10</sub> 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<sub>10</sub> reduction for vegetative microorganisms or a 4 Log<sub>10</sub> 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:

$$\text{Log}_{10}\text{RC} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{NR},$$

where: Log<sub>10</sub>RC > 6 for vegetative microorganisms and > 4 for bacterial spores  
and

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

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

$\text{Log}_{10}\text{NR}$  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.  $\text{Log}_{10}\text{NR}$  represents an accountability factor for microbial loss and is defined by the following equation:

$$\text{Log}_{10}\text{NR} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{RC}.$$

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<sub>10</sub> kill") can be calculated by employing the following equation:

$$\text{Log}_{10}\text{ kill} = \text{Log}_{10}\text{IT} - \text{Log}_{10}\text{NR} - \text{Log}_{10}\text{RT},$$

where:  $\text{Log}_{10}\text{ kill}$  is equivalent to the term  $\text{Log}_{10}$  reduction;

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

$$\text{Log}_{10}\text{IT} = \text{Log}_{10}\text{IC};$$

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

$\text{Log}_{10}\text{RT}$  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

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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 addition 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-time 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.



# 4

## PERMITTING AND STATE AUTHORIZATION ISSUES

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STAATT II also reviewed several of the permitting issues identified in STAATT I, as summarized in the following discussions.

### **User Verification: Biological Inactivation Efficacy Monitoring**

User verification methodology is necessary to periodically verify to the equipment's user and the state that the treatment unit is functioning properly, that proper operating procedures are used, and that performance standards are achieved. User verification protocols will employ biological indicators in addition to available verified parametric monitoring. Protocols used will have previously been approved by the state to assure the protocols are congruent with the treatment method/mechanism.

Specifically, to fulfill treatment efficacy and documentation requirements recommended for user verification, the equipment user must:

- Demonstrate that required resistant bacterial endospores (as recommended in Table 2-2) are inactivated to Level III criteria under standard operating procedures
- Establish a frequency of biological and/or parametric monitoring
- Document and record all biological indicator and parametric monitoring data

Since 1994, verification of compliance appears to be more of a state environmental or department of health issue as well as part of the accrediting process of the Joint Commission on Accreditation of Healthcare Organizations under the Environment of Care Standard (see Selected Bibliography). The Occupational Safety and Health Administration (OSHA) continues to focus on issues of occupational safety. User verification requirements recommended are contained in the "State Guideline for Approval of Alternate Medical Waste Technologies" presented in Appendix A.

### **Commercial Versus On-Site Facilities**

Commercial and on-site facilities (i.e., hospitals) can be typically distinguished by the increased volume of waste throughput from commercial facilities. As such, additional

process controls, treatment efficacy monitoring, and permitting are necessitated to ensure effective treatment is maintained and that environmental and occupational/public health and safety concerns are met. As a facility applying for commercial medical waste treatment status, additional permitting requirements may be imposed under other solid or special waste treatment/disposal regulations. As such, cooperative efforts between permitting agencies or divisions is necessitated to ensure the facility is meeting its environmental health and safety responsibilities. To assist in identifying the potential commercial application of a medical waste treatment technology, the STAATT II participants continued to recommend that the potential use of the technology be indicated in technology review information supplied to the state by the equipment manufacturer.

Additionally, while healthcare facilities with on-site treatment capabilities typically treat only their own waste, some have considered accepting waste from off-site facilities and/or transporters. This practice may require additional oversight by regulatory agencies.

## **Previously Approved Technologies**

While the pace of development of new technologies has slowed somewhat, previously granted approvals are still an issue. However, this appears to have been addressed as was initially recommended by STAATT I.

An option that is used today provides the granting of approval for a technology with the provision that any modification to the equipment would require re-application for approval under current standards. As an example, the State of New York Department of Health in its approval letter continues to include the following statement:

“This approval is granted for this specific system used in your efficacy studies and should not be construed as a general endorsement of the technology employed or any other unit or system. Any modifications of the system will require separate approval of the department and may involve further efficacy testing.”

A second option limits the granted site or use permit to a specific time period (e.g., 3 or 5 years). At the time of renewal, the unit must demonstrate that it meets the efficacy criteria and other permit conditions at the levels prescribed in the new standards.

As a third option, the state could mandate that upon the issuance of the new medical waste treatment efficacy standards, pre-existing equipment subject to regulation would be required to comply with current efficacy standards within a set time period. Following compliance, the user would have the option to replace the existing equipment with approved technology, retrofit the equipment to meet current standards, or take the equipment out of service. Incorporation of additional provisions

as stated in Option One or Option Two with those in Option Three would ensure that technology meeting current standards would remain in compliance with future, more restrictive regulations.

Steam sterilizers or autoclaves are not considered “emerging treatment technology.” Steam sterilization process has been used for decades to sterilize medical products, biological products, and medical or biohazardous waste and is generally recognized as a traditional sterilization process. Accordingly, many states still do not consider steam sterilization to be a new technology and do not require any additional approval as such. It is recommended by the STAATT II participants that steam sterilization not be subject to registration and technology approval requirements unless it is to be used for treatment of items such as pathological or chemotherapeutic waste. Site and operation permits, as well as validation and challenge testing, would still be necessitated, as required, under applicable state regulations.

The STAATT I participants, however, did recognize that the steam sterilization process is subject to waste load variables and operator control which could lead to inadequate processing of the waste. To assist in documenting that the process is effective, the equipment operator should:

- Adopt standard written operating procedures which denote the following:
  - Sterilization cycle time, temperature, pressure
  - Types of waste acceptable
  - Types of containers and closures acceptable
  - Loading patterns or quantity limitations
- Document times/temperatures for each complete sterilization cycle
- Use time-temperature sensitive indicators to visually note the waste has been decontaminated
- Use biological indicators placed in the waste load (or simulated load) periodically to verify that conditions are met to achieve decontamination
- Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results

## **Small Medical Waste Treatment Devices**

As stated previously, Level III criteria are applicable to all medical waste treatment devices, including small “counter-top” devices. It was recognized by the STAATT I participants that registration of all small medical waste treatment device users by the authorized state regulatory agency would be a monumental effort. To minimize the state’s effort, it is suggested that the equipment’s manufacturer (or vendor) take responsibility in fulfilling siting requirements as a condition of technology approval. As such, the manufacturer would provide during the technology approval process, all information required of site approval for a typical site for which the equipment is designed. Information required of the small treatment device manufacturer would be similar to the information required of all medical waste treatment equipment manufacturers, but would include all materials and documents required of the user to ensure proper use, safety, and effective treatment. These materials and documents would include the following:

- An operations and maintenance manual
- Information on proper use and potential misuse
- Treatment efficacy testing instructions
- Training/education manual
- Available service agreements/programs

Upon the installation of the treatment device, the manufacturer would complete a record of the buyer, the location, and the results of on-site challenge testing at the time of purchase. This information could be submitted annually to the state by the manufacturer as the notification record of site registrations of equipment installed that previous year. It is recommended that small medical waste treatment devices be specifically identified upon initial application for technology approval.

## **Waste Residue Disposal**

The disposition of waste residues remains an environmental concern in certain parts of the United States. To ensure that waste residues are properly identified and disposed of, the participants continue to recommend that they be addressed at both the technology approval stage and equipment siting stage of the review process. During the technology approval process, information on the characteristic(s) of the waste residues, the mechanism(s), and the mode(s) of their disposal should be provided by the manufacturer. This information should include the following:

- A description of residues (i.e., liquid, solid, shredded, hazardous constituents)

- Waste designation (i.e. hazardous, special, general)
- Disposal mechanisms (i.e. landfilling, incineration, recycling)
- Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort)

During the siting stage of the review process, specific information on residue disposal should also be required. This information should include all of the above information, but specifically state with attached documentation the actual mechanism and location of disposal. To avoid recycling being used as a mechanism to potentially avoid regulatory permitting requirements and to assure that recycling efforts are legitimate, the state should request the following information from the on-site or commercial facility:

- The types of waste residue to be recycled
- The amounts of waste residue to be recycled
- The percentage of the total waste and waste residue to be recycled
- The recycling mechanism used
- The location of the recycler

Previously untreated medical wastes used in the development and testing of prototypical equipment should continue to be considered as potentially infectious and as such, be disposed of as untreated medical waste. To minimize environmental and occupational exposures that may result from using untreated medical wastes, it was recommended that prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid wastes after verification of treatment effectiveness.

It was the consensus of the STAATT II 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 as has already been discussed in Chapter 2 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 (for example, 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.

## **Operator training**

Affecting both treatment efficacy and operator safety, mandated operator training is recommended (as appropriate: small treatment devices may be excluded from this recommendation) as a requirement for process approval. To assure proper operation of the treatment process, the manufacturer would be requested to provide an operator training program which would include:

- Training and education materials adequately describing the process, process monitors and safety controls
- Contingency plans in the event of abnormal occurrences (i.e., power failure, jamming, inadequate chemical concentrations) and emergencies (i.e., fire, explosion, release of chemical or biohazardous materials)
- Personal protective equipment requirements
- A listing of all potential occupational safety and health risks posed by the equipment and its use

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) was reviewed for its potential applicability as a guideline for developing required elements for operator training. Although the participants agreed that the proposed standard was far too extensive for emerging medical waste treatment equipment operations, certain components might provide the basis for an operator training program for other medical waste treatment technologies.

## **Equipment Operations Plan**

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) offers elements for inclusion into an equipment operations plan. Using this proposed standard as a guide, the following components are recommended for incorporation into an equipment operations plan:

- A description of all mechanical equipment, instrumentation, and power controls
- A description of systems' operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal

- A description of all parametric controls and monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements
- A description of the methods required to ensure process monitoring instrumentation is operating properly
- A description of methods and schedules for periodic calibration of process monitoring instrumentation
- A description of proper mechanical and equipment responses, including identification of system upsets (such as power failure, jamming, inadequate treatment conditions) and emergency conditions (for example, fire, explosion, release of chemical or biohazardous materials)
- A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- A description of all potential occupational safety and health risks posed by the equipment and its use
- Assignment of the following responsibilities to specific persons:
  - Collecting and organizing data for inclusion into the operating record
  - Evaluating any discrepancies or problems
  - Recommending actions to correct identified problems
  - Evaluating actions taken and documenting improvement

### **Emergency and Contingency Response Plan**

The development of a separate plan was recommended by the participants to assist the operating facility in properly responding to an unplanned, emergency, or abnormal event. The primary objectives of this emergency and contingency response plan are:

- To prevent or minimize biological and/or chemical agent release to the environment
- To prevent or minimize exposure to the equipment operator or other support or maintenance personnel
- To develop contingency medical waste treatment or disposal alternatives for untreated or inadequately treated waste

The plan should take into consideration those events that result in:

- Failure in the treatment technology (such as inadequate chemical concentration, temperature)
- Mechanical failure (such as a jammed shredder, inadequate steam pressure)
- Equipment shut-down in mid-cycle
- Spill or release of biological or chemical agents
- Accumulation of untreated or inadequately treated medical waste

The development of the plan will by necessity, be a shared responsibility between the manufacturer (vendor) and the equipment's user. As the equipment designer, the manufacturer (vendor) should provide evidence of a failure mode and effect analysis to prevent or minimize inadequate treatment or biological/chemical exposures through process design, process control, and process monitoring. The results of this analysis should be provided through:

- A description of all process controls and process monitoring devices, their appropriate settings, and established ranges and operating parameters (for example, DOP testing of HEPA filters, see Selected Bibliography)
- A description of all parametric controls and associated monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements
- A description of proper mechanical and equipment responses, including identification of system upsets or malfunction (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- A description of the methods required to ensure process and parametric monitoring devices are operating properly
- A description of methods and schedules for periodic calibration of process and parametric control and monitoring instrumentation
- A description of equipment/inadequately treated waste decontamination procedures required in the event of a mid-cycle shut-down

The equipment's user has the responsibility of incorporating the manufacturer supplied information into a descriptive written emergency and contingency response plan. Additional information to be provided within the plan should include:

- A description of all potential occupational safety and health risks posed by the equipment and its use
- A description of proper responses for system upsets and emergency conditions
- A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- A description of proper medical response if required
- A pre-designated disposal site for untreated or inadequately treated medical waste if a mechanical failure precludes the treatment equipment's use

There are some additional items for regulators as well as vendors to be aware of regarding safety of employees. The information comes from a two year study conducted by NIOSH to evaluate biological and chemical exposures in medical waste treatment facilities. These considerations would apply to anyone using any type of treatment device (small or large, on-site or commercial facility).

#### **Recommendations from NIOSH Report (See Selected Bibliography)**

- Perform periodic general safety inspections including checks based on OSHA regulations and other applicable codes. Particular emphasis should be placed on adherence to the electrical code.
- Regularly calibrate and check functioning of testing equipment including battery checks.
- Continue providing regular worker training.
- Do not allow workers to enter the treatment equipment unless absolutely necessary. Explore other options first such as the use of a long handled broom to clean the ventilation screen in the microwave unit. If necessary, make provision for sanitization of the waste and work systems before the worker enters and require the use of protective clothing, gloves, boots, and head protection.
- Provide protective equipment as appropriate to the facility including adequate splash protection.
- Require that protective clothing that was worn in the facility not be worn home. This stricture should include all outerwear.
- Reduce possible transfer of contamination from the waste treatment areas to other areas by having shoes that were worn in the plant changed or covered before the wearer enters an office area.

- Give careful attention to daily routine cleaning and decontamination of treatment units and other facility surfaces.
- Provide areas separate from the medical waste treatment for workers to use for taking breaks and eating lunch.
- Carefully follow and upgrade worker protection programs to include specific glove use protocols based on the situation in each facility and the NIOSH recommendations for glove usage. Suggestions to consider include double gloving where one glove is likely to rip, wearing work gloves over disposable gloves when needed, and consistently using gloves when operating controls.
- Monitor noise levels periodically and require that hearing protection be worn in high noise areas and in any areas specified in hearing protection programs.
- Reconsider waste packaging and handling procedures to minimize worker exposure.
- For future installations or major upgrades, ensure that process design engineers consider the worker-facility-unit interfaces to design out hazards.

# 5

## RESEARCH AND DEVELOPMENT

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STAATT I raised the issue of state responsibility and regulation in the research and developmental phase of medical waste technologies. It was recognized in 1994 that there was a need to develop new technologies, but time, staffing and funding of the permitting state agency might preclude the state's involvement in a research and development project. Concerns raised in state involvement with research and development projects included the following:

- Process of establishing research and development variances, including limitations and allowances
- Knowledge of and permitting of potential environmental emissions and safety considerations
- Treatment process residue disposal
- Agency funding and staffing

The approach suggested by STAATT I in 1994 (language from the State of Illinois Environmental Protection Agency (IEPA) for "experimental permits") is still valid today. IEPA required "applicants to provide proof that the process or technique has a reasonable chance for success. Additionally the IEPA required evidence that "environmental hazards are minimal" and a "description of the type of residuals anticipated and how they will be managed and disposed." As proposed, the experimental permits were to be granted for two years with a one-time renewal based on submittal of application of renewal and a report summarizing equipment performance, treatment efficacy results, and management of residual materials.

It was noted that IEPA stated that the "Agency may issue experimental permits" allowing the IEPA discretion in granting an experimental permit. To minimize concerns that research and development of a medical waste treatment technology may pose environmental and occupation risks, an application form similar to that required of a technology seeking formal approval might be submitted. The form would request available environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary treatment efficacy data and protocols.

To further minimize environmental and occupational safety concerns that might arise during research and development, it was recommended that the prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed as general solid wastes upon verification of treatment effectiveness. Non-treated medical wastes used during research and development would require agency-approved treatment after testing.

The following statements can be adapted into guidance document language:

- Research and development permits are to be granted for a period of two years with a one-time renewal
- Granting of a research and development permit does not assure future site approval at that site upon state approval of the process
- Research and development permitted facilities cannot accept waste for monetary gain
- Research and development permitted facilities must have any experimentally treated medical waste treated by a state approved medical waste treatment process before disposal or recycling

Funding of the additional costs incurred by the state as a result of the increased oversight activities associated with a research and development project can be addressed by some mechanism (such as a set fee for time and materials) established to reimburse the state for these activities.

# 6

## RECOMMENDATIONS FOR FUTURE ACTIVITIES

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The updating of the original STAATT document fulfills one of the recommendations made in 1994 for future activities. Efforts continue moving towards a nationally recognized foundation for the review and approval of emerging medical waste treatment technologies. The American Society for Testing Materials (ASTM) and Underwriters Laboratories (UL) have expressed interest in using the STAATT report in the development of nationally recognized standards for the evaluation of medical waste treatment technologies. Data is also now available on the potential release of biological aerosols from alternative medical waste treatment equipment (See Selected Bibliography—NIOSH Report). To continue with the further development and implementation of a nationally recognized guideline, the participants continue to recommend:

- The establishment of criteria and procedures for emergency and contingency response to ensure adequate equipment decontamination and operator safety in the event of a mid-cycle shut-down or other abnormal occurrence
- The further enhancement of the present clearinghouse to create a network for the following:
  - Future regulatory activities
  - Integration of technology approvals/denials
  - Information on equipment failures
  - Development of emergency equipment decontamination protocols
  - Provision of access to technical expertise and documentation
  - Assistance to manufacturers in the approval process
  - Protocol review/assessment/development/continuity
- Continued committee discussion and interaction with the USEPA Office of Pesticide Programs as that office further develops its registration requirements and protocols for medical waste treatment technologies using chemical agents

- The expanded integration of health and safety oversight of medical waste treatment activities by state regulatory agencies and professional accrediting associations to include defined oversight responsibilities and inspector training programs

As was discussed in the introduction, this STAATT guidance document is not a static work but will continue to change 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.

# 7

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# 8

## GLOSSARY

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“AOAC” refers to the Association of Official Analytical Chemists.

“ATCC” refers to the American Type Culture Collection.

“Biological Indicator(s)” means those microorganisms that are used as representative microbial agents in medical waste treatment efficacy studies and testing.

“cfu” refers to colony forming units.

“Challenge Load” means a medical waste load that has been constructed by composition (i.e., organic content, density, moisture/liquid content, or other physical or chemical composition) or amount to provide an appropriate challenge to treatment effectiveness of the treatment process and microbial inactivating agent.

“Challenge Testing” means microbiological testing conducted periodically on a medical waste treatment technology. Frequency of testing varies according to state statutes and regulations (e.g., weekly, monthly, every 6 months).

“Emerging Alternate Medical Waste Treatment Technology” means any medical waste treatment technology other than incineration and steam sterilization (autoclaving).

“FIFRA” refers to the Federal Insecticide, Fungicide, and Rodenticide Act.

“Log<sub>10</sub> kill” is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment.

“4 Log<sub>10</sub> Reduction” is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population; i.e., a 99.99% reduction.

“6 Log<sub>10</sub> Reduction” is defined as a 6 decade reduction or a 0.000001 survival probability in a microbial population; i.e., a 99.9999% reduction.

“Participants” refers to the State and Territorial Association on Alternate Treatment Technologies.

“Pathogen Surrogate(s)” means those microorganisms that are used as biological indicators in medical waste treatment efficacy studies and testing that represent known microbial pathogens.

“STAATT I” means the State and Territorial Association on Alternative Treatment Technologies guidance document developed as a result of meeting held between 1992 and 1994.

“STAATT II” means the State and Territorial Association on Alternative Treatment Technologies meeting held in New Orleans in the month of February, 1998 to update STAATT I.

“Surrogate Load” means a waste load that has been constructed to represent a typical medical waste load by composition (i.e., organic content, density, moisture or liquid content, or other physical or chemical composition) and amount.

“Validation Testing” means microbiological testing conducted at the time of installation of a medical waste treatment technology.

# A

## STATE GUIDELINES FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

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### Preface

This guideline summarizes the discussions and results of the State and Territorial Association on Alternate Treatment Technologies. It should be emphasized that the recommendations provided by the association and adopted by the participating states are an attempt to find commonality 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, this guideline continues to serve as a model for the development of state guidelines or regulations. It is also recognized that definitions, terms, and regulatory methodologies used within the framework of this guideline may not be compatible with granted legislative authority or existing regulatory language. As such, this guideline may periodically require revision to conform with specific state statutes and regulatory requirements.

### A. Definition of Microbial Inactivation

A1. Inactivation is required to be demonstrated of vegetative bacteria, fungi, lipid/non-lipid viruses, parasites, and/or mycobacteria at a 6 Log<sub>10</sub> reduction or greater; a 6 Log<sub>10</sub> reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction).

A2. Inactivation is required to be demonstrated of *B. stearothermophilus* spores or *B. subtilis* spores at a 4 Log<sub>10</sub> reduction or greater; a 4 Log<sub>10</sub> reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction).

### B. Representative of Biological Indicators

B1. One or more representative microorganisms from each microbial group may be used in treatment efficacy evaluation.

- a) Vegetative Bacteria  
*Staphylococcus aureus* (ATCC 6538)  
*Pseudomonas aeruginosa* (ATCC 15442)
- b) Fungi  
*Candida albicans* (ATCC 18804)  
*Penicillium chrysogenum* (ATCC 24791)  
*Aspergillus niger*
- c) Viruses  
Polio 2 or Polio 3  
MS-2 Bacteriophage (ATCC 15597-B1)
- d) Parasites  
*Cryptosporidium spp.* Oocysts  
*Giardia spp.* cysts
- e) Mycobacteria  
*Mycobacterium terrae*  
*Mycobacterium phlei*\*  
*Mycobacterium bovis* (BCG) (ATCC 35743)\*

B2. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems.

- a) *Bacillus stearothermophilus* (ATCC 7953)\*
- b) *Bacillus subtilis* (ATCC 19659)\*

\* At a minimum, alternative treatment technologies shall tests for these microorganisms.

## C. Quantification of Microbial Inactivation

C1. Microbial inactivation (“kill”) efficacy is equated to “Log<sub>10</sub> kill” which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is equated as:

$$\text{Log}_{10} \text{ kill} = \text{Log}_{10}(\text{cfu/g "I"}) - \text{Log}_{10}(\text{cfu/g "R"})$$

where:

Log<sub>10</sub> kill is equivalent to the term Log<sub>10</sub> reduction.

“I” is the number of viable test microorganisms introduced into the treatment unit.

“R” is the number of viable test microorganisms recovered after treatment.

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

C2. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration can be used to demonstrate treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of treatment efficacy requires a two step approach: Step 1, “Control”; Step 2, “Test.” The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

- a) Step 1:
  1. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.
  2. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals).
  3. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
  4. Plate recovered microorganism suspensions 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).
  5. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction as specified in Section A (i.e., a 6 Log<sub>10</sub> reduction for vegetative microorganisms or a 4 Log<sub>10</sub> reduction for bacterial spores). This can be defined by the following equations:

$$\text{Log}_{10} \text{RC} = \text{Log}_{10} \text{IC} - \text{Log}_{10} \text{NR}$$

or

$$\text{Log}_{10} \text{NR} = \text{Log}_{10} \text{IC} - \text{Log}_{10} \text{RC}$$

where:  $\text{Log}_{10}\text{RC} > 6$  for vegetative microorganisms and  $> 4$  for bacterial spores and where:  $\text{Log}_{10}\text{RC}$  is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) recovered in the non-treated processed waste residue.

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

$\text{Log}_{10}\text{NR}$  is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered after processing.  $\text{Log}_{10}\text{NR}$  represents an accountability factor for microbial loss.

- b) Step 2:
  1. Use microbial cultures of the same concentration as in Step 1.
  2. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the microbial inactivation agent.
  3. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
  4. Plate recovered microorganism suspensions to quantify microbial recovery.
  5. From data collected from Step 1 and Step 2, the level of microbial inactivation (i.e., "Log<sub>10</sub> kill") is calculated by employing the following equation:

$\text{Log}_{10} \text{ kill} = \text{Log}_{10}\text{IT} - \text{Log}_{10}\text{NR} - \text{Log}_{10}\text{RT}$ , where:

$\text{Log}_{10} \text{ kill}$  is equivalent to the term  $\text{Log}_{10}$  reduction.

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

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

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

## **D. Efficacy Testing Protocols**

D1. Methodology employed to determine treatment efficacy of the technology will need to assure required microbial inactivation and assure the protocols are congruent with the treatment method. Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures such as those found in Test Methods for Evaluating Solid Waste, Physical/Chemical Methods and Standard Methods for the Examination of Water and Waste Water.

D2. The Agency shall prescribe those types and compositions of medical wastes that present the most challenge to treatment effectiveness under normal operating conditions of the equipment reviewed.

D3. Dependent on the treatment process and treatment efficacy mechanisms utilized, protocols evaluating medical waste treatment systems shall specifically delineate or incorporate, as applicable:

- a) Waste compositions that typify actual waste to be processed
- b) Waste types that provide a challenge to the treatment process
- c) Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume)
- d) Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process
- e) Assurances of inoculum traceability, purity, viability and concentration
- f) Dilution and neutralization methods that do not affect microorganism viability
- g) Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples/test, number of colony forming units/plate)
- h) Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times)

## **E. Technology Approval Process**

E1. To initiate the technology review process the manufacturer (vendor) shall complete and submit the following information:

- a) 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, pressure, temperatures, chemical concentrations, irradiation doses, feed rates, and waste load composition

- b) Provide documentation demonstrating the treatment method meets microbial inactivation criteria and required testing protocols including a detailed description of the test procedures and calculations used in fulfilling required performance standards verifying treatment efficacy, of user verification methodology, and of microbial culturing protocols which ensure traceability, purity and concentration
- c) Provide information on available parametric controls/monitoring devices, verifying treatment efficacy and ensuring operator non-interference
- d) Provide documentation of applicable emission controls for suspected emissions
- e) Provide information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling
- f) Provide documentation providing occupational safety and health assurance
- g) Provide information on energy efficiency and other potential benefits the treatment technology has to offer to the environment

E2. The manufacturer (vendor) shall demonstrate that all required pathogen surrogates and resistant bacterial endospores are inactivated to criteria specified in Section A and Section C under all Agency specified challenge waste load compositions.

E3. The manufacturer (vendor) shall develop and demonstrate that site approval and user verification testing protocols are workable and valid.

E4. The manufacturer (vendor) shall demonstrate where technically practical, the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

E5. The manufacturer (vendor) shall develop contingency response plans and protocols for use in the event of an emergency, accident, or equipment malfunction. The manufacturer (vendor) shall demonstrate that developed protocols are effective in providing operator safety from physical, chemical, or biological exposures during and after the event including decontamination procedures.

E6. The manufacturer (vendor) shall demonstrate evidence of U.S. EPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

E7. Upon demonstration to the Agency's satisfaction, technology approval granted is granted only under the conditions specified in the 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. Any significant revisions to these equipment and operating conditions, as warranted relevant to the Agency, will require re-application for approval to the Agency.

## **F. Site Approval Process**

F1. To fulfill treatment efficacy and information requirements for site approval, the equipment user shall:

- a) Demonstrate that the equipment sited is the same equipment and process approved by the Agency as specified in Section E
- b) Demonstrate that required resistant bacterial endospores are inactivated as specified in Section A2 criteria under typical waste load and Agency specified challenge compositions
- c) Verify that user verification protocols adequately demonstrate treatment effectiveness
- d) Verify the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment

F2. The site facility shall provide a written operations plan that includes:

- a) The names or positions of the equipment operators
- b) The waste types or categories to be treated
- c) Waste segregation procedures required
- d) Wastes types prohibited for treatment
- e) Equipment operation parameters
- f) Treatment efficacy monitoring procedures
- g) Personal protective equipment requirements
- h) Operator training requirements

F3. The site facility shall provide a written emergency and contingency response plan that includes:

- a) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- b) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- c) A description of all potential occupational safety and health risks posed by the equipment and its use

F4. The site facility shall submit to the Agency for their review:

- a) Equipment model number and serial number
- b) Equipment specification and operations manual
- c) A copy of the facility's operations plan
- d) A copy of the facility's emergency and contingency response plan
- e) Certification documentation of operator training

F5. As a condition of site approval, the Agency shall have a right to inspect the facility and the right 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 plans.

F6. Any modifications to the medical waste treatment unit may require re-approval by the Agency and may involve further efficacy testing.

## **G. User Verification**

G1. To verify that the medical waste treatment unit is functioning properly and that performance standards are achieved, the equipment user shall:

- a) Demonstrate that required resistant bacterial endospores are inactivated to criteria as specified in Section A2 under standard operating procedures using protocols that have previously been approved by the Agency as specified under Section E and F
- b) Establish a frequency of biological monitoring

- c) Document and record all biological indicator and parametric monitoring data

G2. To document treatment efficacy for steam sterilizers and autoclaves, the equipment operator shall:

- a) Adopt standard written operating procedures which denote:
  - 1) Sterilization cycle time, temperature, pressure
  - 2) Types of waste acceptable
  - 3) Types of containers and closures acceptable
  - 4) Loading patterns or quantity limitations
- b) Document times/temperatures for each complete sterilization cycle
- c) Use time-temperature sensitive indicators to visually denote the waste has been decontaminated
- d) Use biological indicators placed in the waste load (or simulated load) periodically to verify conditions meet microbial inactivation requirements as specified in Section A2
- e) Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results

G3. Medical waste incinerators are to be operated, maintained, and monitored as specified in applicable site and operating permits.

## **H. Small Medical Waste Treatment Devices**

H1. All small medical waste treatment devices shall fulfill the requirements necessary for technology approval and shall meet the treatment efficacy requirements as defined in Section A.

H2. Technology and siting approval are the responsibility of the manufacturer or equipment vendor. The manufacturer (vendor) shall provide to the Agency:

- a) All information required for technology approval as defined in Section E
- b) All information required of site approval for a typical site for which the equipment is designed as defined in Section F

- c) All materials and documents required of the user to ensure proper use, safety, and effective treatment

These materials and documents would include:

- 1) An operations and maintenance manual
- 2) Information on proper use and potential misuse
- 3) Treatment efficacy testing instructions
- 4) Training/education manual
- 5) Available service agreements/programs

H3. The manufacturer (vendor) shall furnish the user of the treatment device:

- a) An operations and maintenance manual
- b) Information on proper use and potential misuse
- c) Treatment efficacy testing instructions
- d) Training/education manual
- e) Available service agreements/programs

H4. Upon the installation of the treatment device, the manufacturer shall compile a record of the buyer, the location, and the results of onsite challenge testing at time of purchase. This information shall be submitted annually to the Agency by the manufacturer (vendor) as the notification record of site registrations of equipment installed that previous year.

## **I. Previously Approved Technologies**

I1. Medical waste treatment equipment which is subject to these registration and technology approval requirements that has been installed and operated before January 1, 1998, shall comply with current efficacy standards by (date). By (date), pre-existing medical waste treatment equipment shall have been modified to meet current standards, taken out of service, or replaced by approved equipment.

I2. Steam sterilizers, autoclaves, and incinerators are not included within the category of “emerging treatment technologies” and are not subject to these registration and technology approval requirements. Site and operation permits are still necessitated, as required, under applicable state regulations.

## **J. Waste Residue Disposal**

J1. Information on the characteristic(s) of all waste residues (liquids and solids), and the mechanism(s) and mode(s) of their disposal shall be provided by the manufacturer on the "Evaluation of Medical Waste Treatment Technology: Information Request Form." This information will include:

- a) Description of residues (i.e., liquid, solid, shredded, hazardous constituents)
- b) Waste designation (i.e. hazardous, special, general)
- c) Disposal mechanism (i.e. landfilling, incineration, recycling)
- d) Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort)

J2. Information on waste residue disposal shall be provided by the user facility as required under site approval (Section F). This information shall include:

- a) All information requested in Section J1
- b) The site of disposal (name and address)
- c) The mechanism of disposal (i.e. landfilling or incineration)
- d) The amounts of residue(s) anticipated to be disposed (e.g., volume and weight per week)

J3. If residue(s) are to be recycled the following information shall be provided by the user facility as required under site approval (Section F). This information shall include:

- a) The types of waste residue to be recycled
- b) The amounts of waste residue to be recycled
- c) The percentage of the total waste and waste residue to be recycled
- d) The recycling mechanism used
- e) The name and location of the recycler

J4. Previously untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed as untreated medical waste.

J5. Prototypical equipment testing using non-infectious or previously treated medical waste (i.e., treated by an approved process such steam sterilization) that has been inoculated with recommended pathogen surrogates can be disposed as general solid waste after verification of treatment effectiveness.

J6. All liquid and solid waste residues will be disposed of in accordance with applicable state and local regulations.

## **K. Operator Training**

K1. To assure proper operation of the treatment process, the manufacturer (vendor) shall provide to the user as part of the treatment equipment purchase an operator training program which will include:

- a) A description of all mechanical equipment, instrumentation, and power controls
- b) A description of system's operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal
- c) A description of all parametric controls and monitoring devices, their appropriate settings as correlated with biological indicators, and calibration requirements
- d) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- e) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- f) A description of all potential occupational safety and health risks posed by the equipment and its use

K2. The facility shall develop a written equipment operations plan which will include:

- a) Responsibility delegation for safe and effective equipment operation to operating personnel
- b) A description of operating parameters that must be monitored to ensure effective treatment
- c) A description of all process monitoring instrumentation and established ranges for all operating parameters

- d) A description of the methods required to ensure process monitoring instrumentation is operating properly
- e) A description of methods and schedules for periodic calibration of process monitoring instrumentation

K3. The facility shall develop a written contingency and emergency response plan to include:

- a) A description of all potential occupational safety and health risks posed by the equipment and its use
- b) A description of proper responses for system upsets and emergency conditions
- c) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- d) A description of proper medical response if required
- e) A pre-designated disposal site for untreated or inadequately medical treated waste if a mechanical failure precludes the treatment equipment's use

K4. The facility shall document and keep on record copies of all training for at least 3 years.

## **L. Research and Development**

L1. The Agency may issue an Experimental Permit for medical waste treatment processes or techniques that are undergoing research and development if the applicant can provide evidence that:

- a) Environmental impact is minimal
- b) Occupational exposures are minimal

L2. The Agency's "Evaluation of Medical Waste Treatment Technology: Information Request Form" shall be submitted and shall contain environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary treatment efficacy data and protocols.

L3. All equipment testing shall preferably use non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates listed in Section B. Waste residues generated can be disposed as general solid wastes upon verification of

treatment effectiveness. Untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed as untreated medical waste.

L4. All Experimental Permits have a duration not to exceed two years with a one-time renewal.

L5. Granting of an Experimental Permit does not assure future site approval upon state approval of the process.

L6. Facilities with experimental permits cannot accept waste for monetary gain.

# *B*

## TREATMENT EFFICACY TESTING PROTOCOL FOR A GRINDER/CHEMICAL MEDICAL WASTE INACTIVATION PROCESS

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### I. Materials

A. *Bacillus stearothermophilus* spores as a suspension of  $2 \times 10^{10}$  initial inoculum. [*B. stearothermophilus* spores were chosen as the spore of choice due to the thermophilic nature of *B. stearothermophilus* and its ability to optimally grow at elevated temperatures. Culturing collected waste samples at 60°C using *B. stearothermophilus* spores as a biological indicator reduces the number of potential cross contaminants that might arise on a culture plate. A spore suspension of  $2 \times 10^{10}$  initial inoculum was chosen to provide an adequate number of recoverable spores for determining a 4 Log<sub>10</sub> reduction. Determination of this concentration may require trial runs to ascertain the recovery concentrations.]

B. Surrogate waste load to be constructed to contain by weight: 5% organic material and 95% plastics, cellulose, and glass. Total weight of sample to be between 15 and 20 pounds. [The surrogate waste load used in this example was constructed to represent the typical medical waste composition that would be treated by this system at the user site location. Surrogate waste loads may also be constructed to replicate medical waste loads which challenge the treatment efficacy of the system. The sample weight of the load was selected as being representative of the feed rate and typical loading conditions of the unit. Weight loads should be constructed to mimic conditions of actual use.]

### II. Protocols

#### A. Control Run

1. Add  $2 \times 10^{10}$  *B. stearothermophilus* spore suspension to surrogate waste load. [The spore suspension should be added as to not expose the researcher or equipment operator to the biological indicator. To minimize potential exposures and to

adequately disperse the spore suspension throughout the load, the spore suspension could be transferred into four or more separate plastic screw-capped tubes. These tubes could subsequently be equally dispersed throughout the surrogate waste load.]

2. Load inoculated surrogate waste into the previously cleaned (decontaminated) treatment unit and run unit without chemical inactivation agent. [The unit should be previously decontaminated to minimize cross contamination from spores originating from previous efficacy testing.]
3. Collect ten 1-gram samples during the duration of the run (i.e., collect samples at the beginning of waste discharge through final discharge). [The amount, number and collection frequency of sample collection will be determined previously by trial runs. The important consideration for this determination is to ensure that during the span of the run, the test data collected provide an accurate reflection of treatment efficacy for the entire load.]
4. Place the 1-gram samples immediately upon collection into pre-weighed (combination weight of both liquid and tube) plastic screw cap tubes containing an appropriate neutralizing solution and vortex vigorously for 5 minutes. [This step is required to neutralize chemical agent activity at the time the waste exits the unit and is necessary to determine actual treatment efficacy during the treatment process and minimize the inclusion of residual chemical activity that might be present. The amount, concentration, and exposure time of the selected neutralizing agent must be pre-determined so as to neutralize the specific chemical agent without inhibiting growth of the biological indicator. Collection tubes are pre-weighed, including neutralizing agent, to determine the weight of the actual waste sample collected.]
5. Construct an approximate 10-gram composite sample from the 10 representative samples collected in Step 3. [This step provides for the evaluation of treatment efficacy of the entire load without assaying each individual sample taken above.]
6. Decant, sieve, and filter as required to separate solid waste material from the neutralizing liquid. Save liquid effluent. [This step is required to wash bacterial spores from the collected waste sample. Protocols involved in this rinsing step will be determined by trial runs to ascertain the best mechanisms to adequately rinse and separate the solid waste components from the liquid rinse.]
7. Wash and vortex solid materials a second time with neutralizing buffer. Decant, sieve, and filter as required to separate solid waste material from liquid. Combine liquid effluent with that obtained in Step 6. [This step provides an extra wash to collect from the waste as many of the spores as possible.]
8. Filter liquid through Millipore™ filtration unit or equivalent to concentrate retrieved spores on membrane filter. Wash filter with 10 mls of citrate or other appropriate

buffer. [This step concentrates retrieved spores to equal the number of spores from 10 grams waste/10 mls buffer or by factoring, the number of spores from 1 gram waste per 1 ml buffer. For example, plating one ml of the liquid would result in the number of cfu's on the plate to be equal to the number spores per one gram of waste.]

- a) Triplicate plate 0.1 ml from the 10 ml concentrate in Step 8 above; this dilution represents Plate A. [This step equates to a total dilution of 1:10.]
- b) Add 1.0 ml of the 10 ml concentrate in Step 8 above to 9.0 mls of buffer solution (this represents a 1:10 serial dilution and is represented as Dilution Tube B). Triplicate plate 0.1 ml of Dilution Tube B; this dilution represents Plate B. [This step equates to a total dilution of 1:100.]
- c) Add 1.0 ml of Dilution Tube B above to 9.0 mls of buffer solution (this represents an additional 1:10 serial dilution and is represented as Dilution Tube C). Triplicate plate 0.1 ml of Dilution Tube C; this dilution represents Plate C. [This step equates to a total dilution of 1:1000].
- d) Add 1.0 ml of Dilution Tube C above to 9.0 mls of buffer solution (this represents an additional 1:10 serial dilution and is represented as Dilution Tube D). Triplicate plate 0.1 ml of Dilution Tube D; this dilution represents Plate D. [This step equates to a total dilution of 1:10,000].

## **B. Test Run**

1. Follow protocols in II A, except run the treatment unit with specified chemical inactivation agent concentrations.
2. Upon washing the membrane filter in Step II. 8 with 10 mls of buffer.
  - a) Triplicate plate 1 ml of buffer in Step 2 above via the pour plate method (i.e., 1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate A'. [This step equates to no dilution factor, i.e., this number represents the number of spores per gram of waste.]
  - b) Triplicate plate 0.1 ml of buffer in Step 2 above via the pour plate method (i.e., 0.1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate B'. [This step equates to a 1:10 dilution factor.]
  - c) Add 1.0 ml of the buffer in Step 2 above to 9.0 mls of buffer solution (this represents a 1:10 serial dilution and is represented as Dilution Tube C'). Triplicate plate 0.1 ml of Dilution Tube C'; this dilution represents Plate C'. [This step equates to a total dilution of 1:100.]

### III. Calculations

Using the equations found in Section C3 of “State Guideline for Approval of Alternate Medical Waste Technologies”, the following calculations are performed:

A. Calculate initial inoculum in spores per gram waste.

$$\begin{aligned} 2 \times 10^{10} \text{ spores}/15 \text{ lbs. waste} &= \\ 2 \times 10^{10} \text{ spores}/6.8 \times 10^4 \text{ grams waste} &= \\ 3 \times 10^6 \text{ spores/gram waste} &= \text{inoculum} = \text{IC}. \end{aligned}$$

$$\text{IC} = 3 \times 10^6$$

B. Calculate number of spores recovered.

1. Step One “Control” Data:

	a	b	c
Plate A	TMTC*	TMTC	TMTC
Plate B	TMTC	TMTC	TMTC
Plate C	TMTC	TMTC	TMTC
Plate D	200 cfu**	210 cfu	190 cfu

\*Too Many To Count

\*\*Colony Forming Units

Accounting for the dilution factor of 10,000 for Plate D, the average recovery of viable “Control” spores per gram equals  $200 \times 10,000$  or 2,000,000 spores/gram or  $2 \times 10^6$  spores/gram.

$$\text{RC} = 2 \times 10^6 .$$

2. Step Two "Test" Results:

	a	b	c
Plate A'	50 cfu	48 cfu	52 cfu
Plate B'	5 cfu	4 cfu	6 cfu
Plate C'	1 cfu	0 cfu	0 cfu

The average recovery of viable "Test" spores per gram equals 50 spores per gram (no dilution factor).

$$RT = 5 \times 10^1$$

C. Calculate Log<sub>10</sub> Reduction.

1. Step One "Control" Results:

$$\text{Log}_{10}\text{RC} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{NR}; \text{ where:}$$

$$\text{Log}_{10}\text{RC} = \text{Log}_{10}(2 \times 10^6 \text{ spores/gram}) = 6.301$$

$$\text{Log}_{10}\text{IC} = \text{Log}_{10}(3 \times 10^6 \text{ spores/gram}) = 6.477$$

$$\text{Log}_{10}\text{NR} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{RC}$$

$$\text{Log}_{10}\text{NR} = 6.477 - 6.301 = 0.176$$

$$\text{Log}_{10}\text{NR} = 0.176.$$

2. Step Two "Test" Results and Log<sub>10</sub> kill Calculation:

- a)  $\text{Log}_{10} \text{kill} = \text{Log}_{10}\text{IT} - \text{Log}_{10}\text{NR} - \text{Log}_{10}\text{RT}$ , where:

$$\text{Log}_{10}\text{IT} = \text{Log}_{10}\text{IC} = 6.477$$

$$\text{Log}_{10}\text{NR} = 0.176$$

$$\text{Log}_{10}\text{RT} = \text{Log}_{10}(5 \times 10^1) = 1.699$$

- b) Log<sub>10</sub> Reduction (Log<sub>10</sub> kill), where:

$$\text{Log}_{10} \text{kill} = 6.477 - 0.176 - 1.699 = 4.602$$

$$\text{Log}_{10} \text{kill} = 4.602$$



# C

## EXISTING MEDICAL WASTE TREATMENT TECHNOLOGIES

**Note: This is only a partial list of technologies. The information presented here is constantly changing. Therefore, it is highly recommended to use other sources for searching out all available potential vendors.**

Type of Technology	Company and Location
<b>Autoclave</b>	
	Aegis Bio-Systems, L.L.C. 3324 French Park Drive, Suite A Edmonds, OK 73034
	Bioclave Systems 161 Ward Court Lakewood, Colorado 80228
	Bondtech Corp 2404 Bardstown Rd Louisville, KY 40205
	Environmental Tectonics 125 James Way Southampton, PA 18966
	Hydroclave Systems 1371 Middle Rd., Kingston, Ontario, Canada K7L 5H6
	Lajtos TDS 28, rue Sebastopol 59100 Roubaix - France
	The Mark-Costello Co. 1145 E Dominguez St # Carson, CA 90746

Type of Technology	Company and Location
	Occigerm 250, Ancienne Route de Cavillargues 30330 Connaux - France
	R.E. Baker SIERRA INDUSTRIES, INC. 1021 South Linwood Ave. Santa Ana, CA 92705
	San-I-Pak, Inc. 23535 South Bird Road P.O. Box 1183 Tracy, CA 95378-1183
	Tempico, Inc. 251 Highway 21 Madisonville, LA 70447
	Tuttnauer USA Co., Ltd. 33 Comac Loop, Ronkonkoma, NY 11779
<b>Chemical/Enzyme/Encapsulation</b>	
	Bio Conversion Technologies Tucker, GA 30084
	Circle Medical Products, Inc. 3950 Culligan Avenue, Suite D Indianapolis, IN 46218
	DI/AN Controls, Inc. 530 West St Braintree, MA 02184
	Isolyser Company 650 Engineering Dr Norcross, GA 30092
	M.C.M. Environmental Technologies Ltd. Moledet, M.P. Gilboa 19130, Israel
	MedCompliance Services 5307 El Paso Drive El Paso, TX 79905
	Kvaerner U.S. Inc. Successor to Mediclean Technology Inc. 116 Roddy Avenue South Attleboro, MA 02703-7974

Type of Technology	Company and Location
	Medwaste Technologies Corp. 6830 N Eldridge Pkwy # 110 Houston, TX 77041
	OBF Industries, Inc. 2719 Curtiss Street Downers Grove, IL 60515
	Premier Medical Technology 9800 Northwest Freeway, Suite 302 Houston, TX 77092
	Safetec of America 1055 East Delevan Avenue Buffalo, NY 14215
	Sterile Technology Industries, Inc. 1155 Phoenixville Pike, Unit 105 Park Valley Corporate Center Westchester, PA 19380
	Steris Corp. 5960 Heisley Road Mentor, OH 44060
	Unitrade Ltd. PO Box 644 Corona Del Mar, CA 92625
	Waste Reduction, Inc.(WR <sup>2</sup> ) 212 Pinewoods Avenue Troy, NY 12180
	WESCO (Formerly Winfield - Condor Medical Waste Treatment System) 114 Fourteenth St., Suites B&C Ramona, CA 92065
<b>Wet or Dry Heat/Electrothermal Radiation</b>	
	The Antaeus Group 1 Northpark Drive , Suite 108 Hunt Valley, MD 21030
	Biosterile Technology, Inc 4104 Merchant Road Fort Wayne, IN 46818

Type of Technology	Company and Location
	MDS Nordion 447 March Road Kanata, Ontario Canada K2K 1X8
	MediVators, Inc. 2995 Lone Oak Circle, Suite 10 Eagan, MN 55121-03878
	PMA Services Inc. 22347 La Palma Ave. Ste. 106 Yorba Linda, CA 92887
	Stericycle, Inc. 1419 Lake Cook Road, Suite 410 Deerfield, IL 60015
	Thermal Waste Technologies 19 Stony Hill Road Bethel, Connecticut 06801
<b>Microwave</b>	
	CMB, Ltd. Mechanical Engineering Environmental Technology and Marketing Plabutscherstrassa 115, A-8051 Graz, Austria
	Meteka Medizinalbedarf Entwicklungs - Erzeugungs- und Handelsges.m.b.H. A-8750 Judenburg, Burggasse 108 Judenburg, Austria
	Roatan Medical Technologies, Inc. PO Box 227377 Dallas, Texas
	Sanitec, Inc 26 Fairfield Place. West Caldwell, NJ 07006
<b>Plasma/Pyrolysis/Gasification</b>	
	BIO-OXIDATION SERVICES INC., a division of Harsco Corp., 613 Third Street Annapolis, MD 21403

<b>Type of Technology</b>	<b>Company and Location</b>
	PEAT, Inc. 4914 Moores Mill Rd Huntsville, AL 35811
	Plasma Pyrolysis Systems, Inc. 105 Jordan Road, NY 12180
	VANCE IDS, Inc. 7382 Chancellor Dr Orlando, FL 32809
	Vanish, Inc. 6300 Highlands Court Ponte Vedra Beach, FL 32082



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