TECHNICAL ASSISTANCE MANUAL: STATE REGULATORY OVERSIGHT OF MEDICAL WASTE TREATMENT TECHNOLOGIES

1.0 INTRODUCTION

The development of new or modified medical waste treatment methods utilizing heat, chemicals, or irradiation has provided potential alternative solutions to the medical waste treatment/disposal problem. However, with the development of these medical waste treatment methods, the concern has arisen that these new technologies may also lead to potential environmental or occupational health and safety exposures. Only a limited number of states have attempted to quantitatively and qualitatively assess the efficacy and safety of these new treatment technologies. For those states that have adopted criteria, there is no universality of approach in the assessment of treatment technology efficacy and safety.

Establishing a uniform guideline or a standard set of efficacy criteria can result in potential benefits to the state approval process. A uniform approach may provide economic benefits through facilitating the state review process via similarity in approval requirements and the avoidance of state-by-state review duplication. Minimizing state liability in the review process is also a potential benefit of standardized, documented efficacy criteria and testing protocols. As another potential benefit, developing nationally recognized protocols and assessment criteria might also enhance facilitation and cooperation between federal and other state agencies integral to or peripherally involved in the review process.

In an attempt to standardize processes for medical waste technology review, several states that had actively participated in the programs authorized under the federal Medical Waste Tracking Act of 1988 organized and conducted a meeting in New Orleans, Louisiana on December 13 and 14, 1992. With the purpose of establishing a framework or guideline for a state approval process for medical waste treatment technologies, particularly those other than steam sterilization or incineration, this meeting initiated discussions on defining medical waste treatment technology efficacy criteria and delineating the components required to establish an effective state approval process. Although much was accomplished at this meeting, many issues remained unresolved.

With the objective of attaining committee consensus on the technical and administrative elements of treatment technology approval, a second meeting was held on February 25 and 26, 1993, in Atlanta, Georgia to continue the discussions initiated at the December 1992 meeting. At this meeting the committee recognized the need for establishing its identity to coordinate and support these activities. As such, the name "State and Territorial Association on Alternate Treatment Technologies" (STA^2T^2) was adopted for the purpose of defining the Committee and its objectives. The term "alternate" was defined as "other than steam sterilization or incineration".

The Atlanta meeting's agenda was based on attaining the committee's consensus on the technical and administrative elements of treatment technology approval. Specific topics addressed and discussed were as follows:

- Definition of the level of recommended microbial inactivation (i.e., Level II or Level III spore inactivation levels);

- Establishment of defined pathogen surrogates for microbial inactivation evaluation including:

  - Vegetative pathogen surrogates
  - Bacterial spore formers;

- Determination 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;

- Adoption of enumeration formulae for efficacy testing protocol quantification;

- Development of a comprehensive process approval application form;

- Development of specific process approval mechanisms for:

  - Commercial facilities
  - Health care facilities
  - Research and development projects
  - Small quantity treatment devices
  - Previously approved technologies;

- Development of criteria specifications and requirements for:

  - Waste residue disposal
  - Operator training
  - Challenge loads;

- Development of specific testing protocols for:

  - State permitting/licensing of the technology
  - Site permitting
  - User verification
  - Processes maintaining/not maintaining biological test indicator integrity;

- The timing and extent of USEPA FIFRA involvement in establishing efficacy criteria and protocols.

At the conclusion of the Atlanta meeting a report was prepared entitled "Recommendations for State Regulatory Oversight of Medical Waste Treatment Technologies" which summarized the issues and recommendations discussed during both the New Orleans and Atlanta meetings. This

report was distributed for review and comment to all state and territorial regulatory agencies involved in medical waste regulatory activities.

To gain additional input into the development of a uniform guideline for the assessment of medical waste treatment technologies, a third meeting was conducted on June 14-16, 1993, in Washington, D.C. with invited participants from all state and territorial medical waste regulatory agencies. The report prepared from the Atlanta meeting served as a basis of discussion. With invited input from all state and territorial representatives, the primary objective of the meeting was to seek consensus on the key topic areas listed above.

This report details the discussions and recommendations of the participants from the three meetings. It should be emphasized that 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. As such, consensus agreement was sought on key issues to demonstrate support for the recommendations made in this report. However, consensus support for a recommendation does not necessarily imply unanimity for the position taken. Recognizing that all states may not totally agree with these recommended criteria or protocols, the guidelines developed through this series of meetings should serve only to provide guidance to states in the development of a review and approval process for medical waste treatment technologies.

Logistical support for all three meetings was provided by the USEPA. Roger Greene, Rhode Island Department of Environmental Management, Diann J. Miele, Rhode Island Department of Health, and Dr. Nelson S. Slavik, President, Environmental Health Management Systems, Inc., cofacilitated each of the meetings. A listing of all participants attending the New Orleans, Atlanta, and Washington, D.C. meetings is found in Appendix D.

2.0 MEDICAL WASTE TREATMENT TECHNOLOGY EFFICACY ASSESSMENT CRITERIA

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

Currently, there are no federal or national efficacy standards for medical waste treatment technologies and only a limited number of states have attempted to establish treatment efficacy criteria. The need exists to develop nationally recognized standard treatment performance criteria and operating protocols which establish the qualitative and quantitative parameters that ensure effective treatment. This section provides recommended medical waste treatment technology efficacy assessment criteria and discusses the rationale for their recommendation.

2.1 Classification of Emerging Medical Waste Treatment Technologies

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

- Thermal (wet and dry heat, microwaving, infrared, laser, plasma pyrolysis)
- Chemical (chlorine, chlorine derivatives, ozone, enzymes)
- Irradiation (UV, Cobalt 60)
- Other treatment mechanisms designed for specific medical waste categories generated in small volumes (thermal/electrical).

For certain technologies, there may be a combination of inactivation modes used to inactivate microorganisms (i.e., chemical/thermal or chemical/irradiation). In addition to the treatment mode, there may also be - mechanical grinding introduced prior to, during, and/or at the end of the treatment process (Note: Grinding, shredding, and compaction are not viewed as treatment methods, but are used to facilitate the effectiveness of the treatment method or to render the waste destroyed, unrecognizable and nonfunctional). 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.

2.2 Definition of Microbial Inactivation

Underlying the development of assessment protocols for approving an emerging medical waste treatment technology, is the establishment of efficacy criteria that provide a quantitative and qualitative measure of required performance. There is no consensus among the states on the level of microbial inactivation required of a medical waste treatment process. To properly define microbial inactivation requires that definitions established include both qualitative and quantitative aspects. From this perspective, definitions need to be established which qualitatively define microbial inactivation (i.e., form and type of microorganisms affected) and which quantify the required level of inactivation.

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

Disinfection can be defined as a procedure that 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 (i.e., 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 all bacteria except Mycobacterium tuberculosis and M. bovis, lipid-enveloped and medium-sized viruses (e.g., herpes simplex virus, cytomegalovirus, respiratory syncytial virus, hepatitis B virus, and human immunodeficiency virus), and 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 (e.g., 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.

It was agreed during the New Orleans meeting that there was a need to establish a separate classification system that would specifically denote levels of microbial inactivation required of

medical waste treatment. This classification system should quantitatively and qualitatively define the measure of required performance. To aid in the establishment of a separate classification system, the following categories of microbial inactivation were offered and discussed.

Level I - Inactivation of vegetative bacteria, fungi, and lipophilic virus

Level II - Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria

Level III - Inactivation of vegetative bacteria, fungi, all viruses, mycobacteria, and B. stearothermophilus spores at 10^4 or greater; or B. subtilis spores at 10^4 or greater with chemical treatment

Level IV - Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria, and B. stearothermophilus spores at 10^6 or greater

At the New Orleans meeting most participants generally favored Level III criteria for 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 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 efficacy evaluation processes; and
- Assigning inactivation levels required of a medical waste treatment technology.

To assist the committee in further defining Levels I-IV, a summary was provided at the Atlanta meeting of USEPA sponsored research 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. It was stated that the research material presented was not yet available for review since this material will serve as an appendix to the USEPA's "Final Report to Congress" when finalized.

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

In defining microbial inactivation levels, each level will require characterization by (1) the microbial groups to be inactivated and (2) the level of microbial inactivation required for each group. 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 committee'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 are reflected in the definition for the Levels of Microbial Inactivation presented in Table I.

It should be noted that the inactivation levels defined in Table I are not to be construed as having any relationship with microbial inactivation requirements for microorganisms in Biosafety Levels I-IV as defined within guidelines set by the Centers for Disease Control in Biosafety in Microbiological and Biomedical Laboratories, (1993).

Inactivation of spores from both B. stearothermophilus and B. subtilis is also defined in Levels III and IV (Refer to Table 1). 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.

TABLE I - LEVELS OF MICROBIAL INACTIVATION

Level I - Inactivation of vegetative bacteria, fungi, and lipophilic viruses at a 6 Log_{10} reduction or greater

Level II - Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater

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

Level IV - Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, mycobacteria, and B. stearothermophilus spores a 6 Log_{10} reduction or greater.

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 USEPA 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). These data indicate 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 committee recommended that either B. stearothermophilus or B. subtilis spores be used as biological indicators for chemical or thermal treatment processes. The question arose, however, 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 I.

The use of B. stearothermophilus or B. subtilis spores for demonstrating microbial inactivation by irradiation processes was also recommended. B. pumilus spores are used as the standard biological indicator to demonstrate irradiation efficacy in the sterilization of medical products. B. pumilus spores are, however, not as resistant to irradiation as the enteroviruses or the vegetative bacterium Deinococcus radiodurans. The use of an enterovirus (e.g., Polio 2 or Polio 3) or Deinococcus radiodurans can provide a more stringent measure of microbial inactivation than B. pumilus spores, making any requirement for this specific Bacillus species unnecessary for the purpose of providing an additional "margin of safety". To demonstrate that bacterial spores can be effectively inactivated, B. subtilis or B. stearothermophilus spores can serve as equivalent biological indicators. Inactivation of B. stearothermophilus or B. subtilis spores, although less resistant to irradiation than B. pumilus spores, serves 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 committee state that inactivation is required of "vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria." Although implied but not specifically stated, this definition requires complete inactivation of the representative microorganisms tested in each of the microbial groups listed. Since complete inactivation is impossible to prove, it can be expressed as a probability function in terms of the number of microorganisms surviving a particular treatment process. In defining sterilization, this function is usually expressed as a 6 Log_{10} reduction. A 6 Log_{10} reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction). Using th definition as a basis for quantifying complete inactivation, the recommendation was made

6 Log_{10} reduction be required of the representative microorganisms tested in each of the microbial groups listed (with the exception of B. stearothermophilus or B. subtilis spores). Table I - Levels of Microbial Inactivation incorporates these revisions.

For inactivation levels required of B. stearothermophilus or B. subtilis spores, the original definition stated that inactivation was required at "10^4 or greater" (i.e., 4 Log_{10} reduction or greater). It was questioned whether this level should remain as stated in the definition or be modified to be less or more stringent. In the USEPA sponsored studies it was demonstrated that of the medical waste treatment technologies studied, all could meet at least a 4 Log_{10} reduction of B. stearothermophilus or B. subtilis spores. The committee supported the level as defined in the original definition. Language however, was modified to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction. A 4 Log_{10} reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction). The committee also revised the Level IV definition to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction. No further revision was suggested. These revisions are reflected in Table I.

Recommendations made by the committee for establishing a quantitative and qualitative definition for the Levels of Microbial Inactivation are incorporated into Categories I-IV of Table I. Summarizing, the committee recommended that:

- Pathogen surrogates representing vegetative bacteria, fungi, parasites, lipophilic/hydrophilic viruses, mycobacteria, and bacterial spores be used to demonstrate microbial inactivation;

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

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

- A 4 Log_{10} reduction level 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 committee on which category would serve as the benchmark criteria for medical waste treatment technology 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;