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

April 1994

A Report of the State and Territorial Association
on Alternate Treatment Technologies

TABLE OF CONTENTS

EXECUTIVE SUMMARY

GLOSSARY

1.0 INTRODUCTION 1

2.0 MEDICAL WASTE TREATMENT TECHNOLOGY EFFICACY ASSESSMENT CRITERIA 4

2.1 Classification of Emerging Medical Waste Treatment Technologies 4
2.2 Definition of Microbial Inactivation 5
Table I - Levels of Microbial Inactivation 8
2.3 Representative Biological Indicators 12
Table II - Recommended Biological Indicators 13
Table III - Biological Indicator Selection Criteria 14
2.4 Quantification of Microbial Inactivation 16

3.0 PROCESS FOR APPROVING MEDICAL WASTE TREATMENT TECHNOLOGIES 19

3.1 Biological Inactivation Efficacy: Establishing Protocols 19
3.2 Approval of Medical Waste Treatment Technologies 21
3.3 Parametric Monitoring and Controls 23
3.4 Site Approval for Medical Waste Treatment Technologies 24
3.5 USEPA Pesticide Use Registration 25

4.0 PERMITTING AND STATE AUTHORIZATION ISSUES 27

4.1 User Verification: Biological Inactivation Efficacy Monitoring 27
4.2 Commercial Versus On-Site Facilities 27
4.3 Previously Approved Technologies 28
4.4 Small Medical Waste Treatment Devices 29
4.5 Waste Residue Disposal 30
4.6 Operator Training. 31
4.7 Equipment Operations Plan. 32
4.8 Emergency and Contingency Response Plan 33

5.0 RESEARCH AND DEVELOPMENT. 35

6.0 RECOMMENDATIONS FOR FUTURE ACTIVITIES 37

7.0 SELECTED BIBLIOGRAPHY 38

APPENDIX A - STATE GUIDELINE FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES A-1

APPENDIX B - APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES B-1

APPENDIX C - EXAMPLE: MICROBIAL INACTIVATION TESTING PROTOCOL FOR A GRINDER/CHEMICAL MEDICAL WASTE INACTIVATION PROCESS C-1

APPENDIX D - LIST OF PARTICIPANTS D-1

EXECUTIVE SUMMARY

I. Introduction

The purpose of this report is to establish a framework or guideline that defines medical waste treatment technology efficacy criteria and delineates 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 states in the development of an approval process for 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:

- Medical Waste Treatment Technology Efficacy Assessment
- Medical Waste Treatment Technology Approval Process
- Permitting and Site Authorization Issues
- Research and Development

II. Medical Waste Treatment Technology Efficacy Assessment Criteria

This report recommends that all medical waste treatment technologies meet the following microbial inactivation criteria:

> 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.

In meeting these 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 and are based on microbial inactivation ("kill") efficacy as equated to "Log_{10} Kill", which is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment.

III. Process for Approving Medical Waste Treatment Technologies

This report recommends that both state and site approval be attained for the use of any 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 microbial inactivation requirements under actual operating conditions; and
- USEPA 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 are achieved.

IV. 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 for microbial inactivation monitoring
- Commercial versus on-site facilities
- Previously approved technologies
- Small medical waste treatment devices
- Waste residue disposal
- Operator training
- Equipment operations plan
- Emergency and contingency response plan

V. 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 limitations and allowances;
- Potential environmental emissions and occupational exposures;
- Treatment process residue disposal; and
- Agency funding and staffing.

This report also provides supplementary materials to assist a state in developing guidelines, an information request form, and microbial inactivation testing protocols. These materials are located in the Appendices A-C under the following headings:

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

GLOSSARY

"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 inactivation 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 the treatment process and microbial inactivating agent.

"Committee" refers to the State and Territorial Association on Alternate Treatment Technologies.

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

"IEPA" refers to the Illinois Environmental Protection Agency.

"Log_{10}Kill" is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment.

"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.

"6 Log_{10}Reduction" is defined as a 6 decade reduction or a 0.000001 survival probability in a microbial population; i.e., a 99.9999% reduction.

"Microbial Inactivation" is defined in Section 2.2 of this document

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

"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.

"Treatment" is defined as a mechanism (such as treatment, chemical, irradiation, etc.) which inactivates microbial organisms.

"USEPA" refers to the United States Environmental Protection Agency.