APPENDIX A

STATE GUIDELINE FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

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 can serve as a foundation or 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 require revision to conform with specific state statutes and regulatory requirements.

STATE GUIDELINE FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

A. DEFINITION OF MICROBIAL INACTIVATION

A1. Inactivation is required to be demonstrated of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; 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).

A2. Inactivation is required to be demonstrated of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater; 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).

B. REPRESENTATIVE BIOLOGICAL INDICATORS

B1. One or more of the following representative microorganisms from each microbial group shall be used to determine if microbial inactivation requirements are met:

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) B. stearothermophilus (ATCC 7953)
b) B. subtilis (ATCC 19659).

C. QUANTIFICATION OF MICROBIAL INACTIVATION

C1. Microbial inactivation ("kill") efficacy is 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. This definition is equated as:

$$Log_{10}Kill = Log_{10}(cfu/g\ "I") - Log_{10}(cfu/g\ "R")$$

where:

$Log_{10}Kill$ is equivalent to the term Log_{10} 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; and

"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 microbial inactivation. 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 microbial inactivation 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 treatment 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 treatment 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_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for bacterial spores). This can be defined by the following equations:

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

or

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

where:

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

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

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

$Log_{10}NR$ is the number of "Control" microorganisms

(in colony forming units per gram of waste solids) which were not recovered in the non-treated processed waste residue. $Log_{10}NR$ 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 treatment 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_{10} Kill") is calculated by employing the following equation:

$$Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$$

where:

$Log_{10}Kill$ is equivalent to the term Log_{10} reduction;

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

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

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

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 USEPA "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" and APHA et al., Standard Methods for the Examination of Water and Waste Water.

D2. The state agency reviewing medical waste treatment technologies (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 microbial inactivation 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); and

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 "Evaluation of Medical Waste Treatment Technology: Information Request Form" to the Agency. The manufacturer (vendor) shall:

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 microbial inactivation, 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 microbial inactivation 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; and

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 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 USEPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

E7. Upon demonstration to the Agency's satisfaction, technology approval 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. 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 microbial inactivation requirements 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 microbial inactivation; and

d) Verify the 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) Microbial inactivation monitoring procedures;

g) Shut-down, clean-out and maintenance procedures;

h) Personal protective equipment requirements; and

i) 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; and

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) Certification that equipment is identical to the state authorized system;

d) A copy of the facility's operations plan;

e) A copy of the facility's emergency and contingency response plan; and

f) 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) Demonstrate adherence to the frequency of biological monitoring specified by the Agency; and

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

G2. To document microbial inactivation 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 that conditions meet microbial inactivation requirements as specified in Section A2; and

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 microbial inactivation 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; and

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) Microbial inactivation testing instructions;

4) Training/education manual; and

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) Microbial inactivation testing instructions;

d) Training/education manual; and

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 on-site 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, 1994, 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 "Application for Evaluation and Approval of Medical Waste Treatment Technologies." This information shall 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); and

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 disposal site (name and address);

c) The mechanism of disposal (i.e. landfilling or incineration); and

d) The amounts of residue(s) anticipated to be disposed of (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; and

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 of as untreated medical waste.

J5. Prototypical equipment testing 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 can be disposed of as general solid waste after verification of microbial inactivation.

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 shall include:

a) A description of all mechanical equipment, instrumentation, and power controls;

b) A description of system operations including waste types acceptable

loading parameters, process monitors, treatment conditions, and residue disposal procedures;

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 procedures to be followed during emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials);

e) A description of the procedures for equipment shut-down and clean-out for maintenance or other purposes;

f) A description of personal protective equipment requirements for routine, abnormal, and emergency operations; and

g) 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 shall include:

a) Delegation of responsibility for safe and effective equipment operation to operating personnel;

b) A description of operating parameters that must be monitored to ensure microbial inactivation;

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; and

f) A description of the procedures for equipment shut-down and clean-out for maintenance or other purposes.

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; and

e) A pre-designated disposal site for untreated or inadequately treated medical waste if a mechanical failure precludes use of the treatment equipment.

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; and

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 microbial inactivation 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 of as general solid wastes upon verification of microbial inactivation. Untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed of 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 on state approval of the process.

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