APPENDIX B

APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

The "Application for Evaluation and Approval of Medical Waste Treatment Technologies" is provided as a guidance document to assist state agencies in reviewing new medical waste treatment technologies. The document is intended to serve only as a model for state development of initial application forms by providing a general format of pertinent technology review questions. Definitions and terms used in this document may require revision to conform with specific state legislative and regulatory requirements.

APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES:

Complete the following questionnaire and return it along with the application. Please include any additional support data which maybe applicable. Use additional paper if necessary. Reference with the related section and number(s).

A. GENERAL

A1. Is the treatment technology best suited for on-site use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving waste from several generators?

On-site_____ Commercial/Regional_____ Both_____

A2. Is this treatment technology specified for use at small generator facilities such as physician, dental, or veterinary offices or clinics?

Yes_____No_____

A3. Has this treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.

A4. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)?

A5. Has the use of this equipment ever resulted in any injuries, of any kind, or transmissions of any disease to any person? Describe all such instances.

A6. Have you reviewed all applicable state solid and medical waste regulations for medical waste acceptance, treatment, and disposal?

A7. Have you inquired as to whether any other permits are required? Please enclose agency response and requirements with your application. List all required permits and enclose copies of any permit approvals.

NOTE: Local governments or other agencies may require permits.

B. LEVEL OF TREATMENT

B1. Does the level of microbial inactivation achieved by the treatment process meet the following definition?

"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."

Yes___ No___ If no, specify where the definition is unfulfilled.

C. CHARACTERIZATION OF PROPOSED TREATMENT PROCESS

C1. Please check the appropriate categories that best describe the methods of this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

Chemical	_____	Heat	_____
Mechanical	_____	Shredder	_____
Microwave	_____	Grinder	_____
Hammermill	_____	Irradiation	_____
Plasma Arc	_____	Radiowave	_____
Encapsulation	_____		

Other (specify)_____

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

Please identify if the proposed system is compatible or non-compatible with the following types of waste.

	Type of Waste	Compatible	Non-compatible
D1.	Cultures and stocks of infectious agents and associated biologicals	_____	_____
D2.	Liquid human and animal waste including blood and blood products and body fluids	_____	_____
D3.	Pathological waste	_____	_____

D4. Contaminated waste from animals _____ _____

D5. Sharps _____ _____

D6. Other _____ _____ _____

Please refer to the state medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D7. What waste characteristics present the most challenge to the proposed treatment process:

Organic materials ____

Liquids ____

Density/compaction ____

Other characteristics ____ Specify: _____

_____

D8. Describe by composition (i.e., material and percentage) those medical wastes that would pose the most challenge to the proposed technology. Why?

D9. Describe the physical or chemical components of medical wastes that would interfere, cause mechanical breakdown, or compromise the treatment process or microbial inactivation efficacy.

E. MICROBIOLOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log_{10} reduction or greater. Bacterial spores shall be inactivated at a 4 Log_{10} reduction or greater. A representative from each of the following microbial groups is required for testing.

E1. Listed below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are any data either to support or refute the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

NOTE: If protocols utilized by the applicant to generate microbial inactivation data are deemed unacceptable by the Department, the Department reserves the right to request that the applicant resubmit data generated from Department-approved protocols. If data has not yet been procured to support the inactivation of the listed biological indicators below, please contact the Department before initiating efficacy testing to ensure research protocols are in accordance with the Department's requirements.

Vegetative Bacteria

- Staphylococcus aureus (ATCC 6538) ___
- Pseudomonas aeruginosa (ATCC 15442) ___

Fungi

- Candida albicans (ATCC 18804) ___
- Penicillium chrysogenum (ATCC 24791) ___
- Aspergillus niger ___

Viruses

- Polio 2 or Polio 3 ___
- MS-2 Bacteriophage (ATCC 15597-B1) ___

Parasites

- Cryptosporidium spp. oocysts ___
- Giardia spp. cysts ___

Mycobacteria

- Mycobacterium terrae ___
- Mycobacterium phlei ___
- Mycobacterium bovis (BCG) ATCC 35743) ___

Bacterial Spores

- B. stearothermophilus (ATCC 7953) ___
- B. subtilis (ATCC 19659) ___

E2. Were the results certified by an independent public health or certified testing laboratory? Yes____ No____

If yes, indicate the name, address, and telephone number of the certifying laboratory and attach the test protocol, results and an explanation of any available data not supporting the reduction factors referenced above.

F. BY-PRODUCTS AND DISCHARGES OF THE TREATMENT PROCESS

F1. Please indicate all by-products and discharges (to air, water, or land) which may be generated as a result of this alternative treatment technology.

Stack Emissions___	Heat___	Slag___	Vapors or Fumes___
Ash___	Liquid___	Smoke___	Aerosols___
Leachate___	Dust___	Odor___	Steam___

Chemical Residues___

Other, specify_____

F2. If any of the above by-products or discharges are indicated, how will they be controlled?

F3. If there are no by-products or discharges indicated, how was this determined?

F4. Are any of these by-products or discharges USEPA-listed hazardous wastes (40 CFR Part 261), biohazardous, etc.? No___ Yes___. If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

G. ENVIRONMENTAL EFFECTS OF THE TREATMENT PROCESS

G1. Are any negative effects on the environment anticipated from the use of the treatment process and/or disposal of the treated waste from the treatment process?

G2. What environmental, occupational, and/or public health hazards would be associated with a malfunction of the treatment process? Specify.

G3. If the treatment process includes the use of water, steam, or other liquids, how will this waste discharge be handled (i.e., sewer, recycled, etc.)? Specify.

G4. What are the physical characteristics of the waste residues generated from the treatment process (i.e., wet, dry, shredded, powdered, etc.)? Specify.

G5. How will the treated medical waste from this process be disposed of (i.e., landfill, incineration, recycled, etc.)? Specify.

G6. Are any by-products classified as hazardous waste (40 CFR Part 261)?

Yes___No___- Complete Item A6.

H. OCCUPATIONAL HAZARDS

H1. What are the potential hazards associated with the treatment process?

H2. What hazard abatement/reduction strategies will be used in during the operation of this treatment process (include engineering controls, person protection equipment, etc.)?

H3. What training will the operator(s) of the treatment process receive?

I. CRITICAL FACTORS OF THE TREATMENT PROCESS

I1.	What are the critical factors that influence the specific treatment technology? Specify.
I2.	What are the consequences if these factors are not met? Specify.
I3.	Explain the ease and/or difficulty of operation of the medical waste treatment system. Specify.
I4.	What type of ongoing maintenance is required in the operation of the treatment system? Specify. Maintenance Manual Attached? Yes___ No___
I5.	What emergency measures would be required in the event of a malfunction? Specify.
I6.	How are these measures addressed in an emergency plan or in the operations protocol?
I7.	What is the maximum amount of waste to be treated by this process per cycle?
I8.	How long is a cycle?

J. CHEMICAL INACTIVATION TREATMENT PROCESSES

J1. If the treatment process involves the use of chemical inactivation:

a) What is the name of the active ingredient?

b) What concentrations must be used and maintained?

c) At what pH is the chemical agent active?

d) What is the necessary contact time?

e) If there is any incompatibility with specific materials and surfaces, specify.

f) What is the pH of any end products (i.e., liquid effluents)?

g) List any additional factors or circumstances that may interfere with the chemical's inactivation potential.

J2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?

J3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use? If yes, please attach a copy of the study and test results.

J4. What health and safety hazards may be associated with the chemical (present and long-term)? Specify.

MSDS Attached? Yes___ No___

J5. Is the chemical agent registered for this specific use with the Environmental Protection Agency (USEPA) Pesticide Registration Division? Yes___ No___

If yes, provide the USEPA registration number_____ and a copy of the EPA-approved label instructions for use.

J6. Is the spent chemical agent classified as a hazardous waste by USEPA (40 CFR Part 261) or by other state criteria? Yes___ No___ If yes, specify whether by USEPA or by which state(s)_____.

J7. Is an environmental impact study for the chemical agent available? Yes___ No___ If yes, attach a copy of this information.

K. QUALITY ASSURANCE AND VERIFICATION OF MICROBIAL INACTIVATION

K1. How is the quality assurance of the treatment process addressed? Specify.

K2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system? Specify.

K3. Other than the biological indicators listed in Section E, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? (Please describe and explain.)

K4. How is it determined that the processed waste has received proper treatment? (Check the appropriate item.)

Temperature indicator:	visual only___	continuous___	both___
Pressure indicator:	visual only___	continuous___	both___
Time indicator:	visual only___	continuous___	both___
Chemical concentration indicator:	visual only ___	continuous ___	both ___

Other: Please specify_____

K5. How have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process? Specify.

K6. What is the established process monitor calibration schedule, and what is its frequency of calibration?

K7. How are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.

K8. How are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately affected? Explain.

K9. What failure mode and effect analyses have been performed on the treatment system? Specify and provide.

L. POST-TREATMENT RESIDUE DISPOSAL, RECLAMATION OR RECYCLING

L1. How will the treated medical wastes from this process be disposed of:

Burial in an approved landfill____

Incineration____

Recycled____

L2. If the wastes are to be recycled, provide additional evidence regarding this strategy.

L3. If the wastes are to be recycled, what percentage of the treated waste will be recycled? How will the remainder of the treated waste be disposed of?

M. POTENTIAL ENVIRONMENTAL BENEFITS

M1. Has an energy analysis been conducted on the proposed technology?

Yes___ No___ If yes, specify and provide results of that analysis.

M2. Has an economic analysis been performed on the proposed technology?

Yes___ No___ If yes, specify and provide results of that analysis.

_____

M3. How does this treatment technology improve on existing medical waste treatment and disposal methods? Specify.

M4. What is the potential of this proposed technology for waste volume reduction? Specify._____

N. OTHER RELEVANT INFORMATION AND COMMENTS

All approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy; as well as all safety, competency or training requirements for the users/operators, etc. must also be included.

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CERTIFICATION STATEMENT

I certify that the information requested and contained in this document is accurate and complete and that all existing documentation requested in this application for this system or similar systems is provided. The Vendor, identified below, agrees to provide [state agency] all results of all studies conducted by or for any state, company, agency or country, or any other person as defined at [state regulation], which the vendor conducts, or is in any way aware of, to determine the operational performance of any aspect of the equipment for which authorization to operate in this state is requested on the filing this application. I am aware that regulated medical waste management systems to be operated in this state for regulated medical waste treatment and/or destruction must be identical to the system described in this application for authorization to operate in this state and for which operational data is presented in the application for [state agency] review. Any and all changes in the system and related equipment after this application submittal and [state agency] review and authorization to operate must be submitted in writing to [state agency] prior to use. The [state agency's] permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy regulated medical waste will be reviewed by [state agency] periodically to ensure specifically authorized regulated medical waste technology systems meet currently accepted standards for regulated medical waste management. [State Agency] may modify system operational or performance requirements for systems that received prior authorizations to operate, if warranted to protect human health and the environment.

I am further aware that on reviewing the completed application and the required attachments, [state agency] may have additional questions and require submissions of data and other information deemed necessary regarding this or related medical waste disposal systems. Failure to provide all existing requested information will result in delays in processing the request for authorization to operate. Failure to provide all required information as outlined in the application, or willfully withholding information, may be cause for [state agency] to deny or rescind authorization to operate if [state agency] determines that the information not submitted would have been in any way relevant to its review of this technology.

NAME OF SYSTEM/EQUIPMENT	**MODEL NUMBER**
NAME OF CERTIFYING PERSON (must be a corporate officer)	**TITLE**
SIGNATURE OF CERTIFYING PERSON (must be a corporate officer)	**DATE**
NAME OF PERSON COMPLETING APPLICATION	**TITLE**
NAME OF VENDOR (COMPANY)	**TELEPHONE**
NAME OF DIVISION	**FAX**
ADDRESS	
CITY, STATE & ZIP CODE	