APPLICATION FOR APPROVAL OF ALTERNATIVE TREATMENT TECHNOLOGIES

Please complete all items below. Mark N/A for any that are not applicable. Include any support data that may be applicable. Use additional paper if necessary with a reference to the appropriate section and number(s).

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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 medical waste from several generators?

On-site _____ Commercial/Regional _____ Both _____

A2. Is this treatment technology specified for use at small generator facilities (those that treat less than 220 pounds per month)?

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 injuries of any kind, or the transmission of any disease to any person? Describe all such instances.

A5. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)? Describe all such instances.

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

Yes _____ No _____

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.

Yes _____ No _____ NOTE: Local governments or other agencies may require permits and/or approvals.

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 Log10 Reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log10 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 used by this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

Chemical	____	Grinder	____
Encapsulation	____	Heat	____
Microwave	____	Irradiation	____
Plasma Arc	____	Mechanical	____
Steam	____	Radiowave	____

Other (specify) _____

D. *WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS*

	Type of Waste	Compatible	Non-compatible
D1.	Animal Waste	_____	_____
D2.	Blood & Body Fluids	_____	_____
D3.	Microbiological Waste	_____	_____
D4.	Pathological Waste	_____	_____
D5.	Renal Dialysis Waste	_____	_____

D6. Sharps _____ _____

D7. Surgical Waste _____ _____
Please refer to the state medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D8. What waste characteristics present the greatest challenge to the proposed treatment process.

Organic materials ____ Liquids ____

Density/Compaction ____ Other characteristics ____ Specify: ____

_____

D9. Describe by composition (i.e., material and percentage) those medical wastes that would pose the most challenge to the proposed technology. Why?

D10. Describe the physical or chemical components of medical wastes that would interfere, cause mechanical breakdown, or compromise the treatment process or microbial inactivation efficacy.

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E. *MICROBIOLOGICAL TEST PROCEDURES*

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeast, 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 microbial groups, listed in "E1" below, are required to be tested.

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 that supports or refutes 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. stearothemophilus (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.

Aerosols	____	Leachate	____	Stack Emissions	____
Ash	____	Liquid	____	Steam	____
Chemical Residues	____	Odor	____	Vapors or Fumes	____
Dust	____	Slag	____	_____	____
Heat	____	Smoke	____	_____	____

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 ADEM-listed hazardous wastes (ADEM Administrative Code 335-14)? If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

Yes _____ No _____

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?

Yes _____ No _____

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 according to Division 335-14 of the ADEM Administrative Code? Yes _____ No _____

H. *OCCUPATIONAL HAZARDS*

H1. What training will the operator(s) of the treatment process receive? _____

H2. What frequency will update training be provided? _____

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. What type of ongoing maintenance is required in the operation of the treatment system? Specify (may attach maintenance manual) _____

I4. What emergency measures would be required in the event of a malfunction? Specify _____

I5. What is the maximum amount of waste to be treated by this process per cycle or per hour? _____pounds

I6. How long is a cycle? _____minutes

J. *CHEMICAL INACTIVATION TREATMENT PROCESSES*

Complete this section if the treatment process involves the use of chemical inactivation.

J1. What is the name of the active ingredient? _____

J2. What concentrations must be used and maintained? _____

J3. At what pH is the chemical agent active? _____

J4. What is the minimum contact time? _____ minutes

J5. Specify any incompatibility with specific materials and surfaces._____

_____

J6. What is the pH of any end products (i.e., liquid effluents)? _____

J7. List any additional factors that may interfere with the chemical's inactivation potential.

_____

_____

J8. What is the active life of the chemical agent after it has been exposed to air or medical waste?

_____

J9. 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. _____

J10. Is a MSDS attached? Yes_____ No_____

J11. Is the chemical agent registered for this specific use with the USEPA Pesticide Registration Division? Yes_____ No_____ If yes, provide number _____

J12. Is the spent chemical agent classified as a hazardous waste by Division 335-14 of the ADEM Administrative Code? Yes_____ No_____

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K. *QUALITY ASSURANCE AND VERIFIVATION OF MICROBIAL INACTIVATION*

K1. Specify how quality assurance of the treatment process is addressed. _____

_____

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

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? _____

_____

_____

K4. How is it determined that the processed waste has received proper treatment?

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? _____

_____

K6. What is the established procedure and frequency to calibrate the process monitors (gauges, clocks, computers, etc.)? _____

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

_____

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

_____

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

_____

_____

L. *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.

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 ADEM all results of all studies conducted by or for any state, company, agency, country, or any other person as defined by Division 335-13 of the ADEM Administrative Code, 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 of 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 ADEM's review. Any and all changes in the system and related equipment after this application submittal and ADEM's review and authorization to operate must be submitted in writing to ADEM prior to use. The ADEM permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy regulated medical waste will be reviewed by ADEM periodically to ensure specifically authorized regulated medical waste technology systems meet currently accepted standards for regulated medical waste management. ADEM may modify system operational or performance requirements for systems that receive 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, ADEM 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 this application, or willfully withholding information, may be cause for ADEM to deny or rescind authorization to operate if ADEM determines that the information not submitted would have been in any way relevant to its review of this technology.

Name of system or equipment	Model Number
Name of certifying person (must be a owner, partner, etc.)	Title
Signature of certifying person	Date
Name of Vendor (company)	Telephone
Mailing Address	Fax Number
City, State & Zip Code	E-mail address
Vendor's contact person	Telephone