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).

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**

<table>
<thead>
<tr>
<th>Type of Waste</th>
<th>Compatible</th>
<th>Non-compatible</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1. Animal Waste</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D2. Blood &amp; Body Fluids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D3. Microbiological Waste</td>
<td></td>
<td></td>
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<tr>
<td>D4. Pathological Waste</td>
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<tr>
<td>D5. Renal Dialysis Waste</td>
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</tbody>
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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.

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. 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.

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

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______

K. QUALITY ASSURANCE AND VERIFICATION 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.

<table>
<thead>
<tr>
<th>Name of system or equipment</th>
<th>Model Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of certifying person (must be a owner, partner, etc.)</td>
<td>Title</td>
</tr>
<tr>
<td>Signature of certifying person</td>
<td>Date</td>
</tr>
<tr>
<td>Name of Vendor (company)</td>
<td>Telephone</td>
</tr>
<tr>
<td>Mailing Address</td>
<td>Fax Number</td>
</tr>
<tr>
<td>City, State &amp; Zip Code</td>
<td>E-mail address</td>
</tr>
<tr>
<td>Vendor’s contact person</td>
<td>Telephone</td>
</tr>
</tbody>
</table>

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