SC DEPARTMENT of ENVIRONMENTAL SERVICES

Guide and Application for Alternative Infectious Waste Treatment Technology Approval

South Carolina Department of Environmental Services (SCDES) – Infectious Waste Program

The following information has been assembled to provide guidance to applicants requesting approval of an Alternative Infectious Waste Treatment Technology in South Carolina. These procedures apply to the approval process for treatment of infectious waste in a manner other than outlined in R.61-105 (e.g., incineration, discharge to a public sewer, steam sterilization, chemical disinfection). The inclusion of any support data requested or available should serve to provide the necessary information to complete the evaluation and decision process. Current State and Territorial Association on Alternate Treatment Technologies (STAATT) recommendations should be followed unless otherwise directed or approved by SCDES.

APPLICATION FOR EVALUATION AND APPROVAL OF INFECTIOUS WASTE TREATMENT TECHNOLOGIES

Complete the following questionnaire and return it along with the application. 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.
- ☐ Yes
- ☐ No

States: _____

A4. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)?
- ☐ Yes
- ☐ No

If Yes, please explain.

A5. Has the use of this equipment ever resulted in any injuries, of any kind, or transmissions of any disease to any person?
- ☐ Yes
- ☐ No

Describe all such instances.

A6. Have you reviewed the Infectious Waste Management Regulations, R. 61-105, for infectious waste acceptance, treatment, and disposal?
- ☐ Yes
- ☐ No

A7. Have you inquired as to whether any other permits are required? Please enclose the SCDES response and requirements with your application. List all agency-required permits and enclose copies of any SCDES permit approvals. NOTE: Local governments or other agencies may require permits.
- ☐ Yes
- ☐ No

B. LEVEL OF TREATMENT

B1. Does the level of microbial inactivation achieved by the treatment process meet the following definition? – *"Inactivation of Geobacillus stearothermophilus spores or Bacillus atrophaeus 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	☐ Hammer Mill	☐ Mechanical	☐ Radiowave
☐ Encapsulation	☐ Heat	☐ Microwave	☐ Shredder
☐ Grinder	☐ Irradiation	☐ Plasma Arc	☐ Other: _____

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	Proposed System
D1. Cultures and stocks of infectious agents and associated biologicals	☐ Compatible ☐ Non-compatible
D2. Liquid human and animal waste including blood and blood products and body fluids	☐ Compatible ☐ Non-compatible
D3. Pathological waste	☐ Compatible ☐ Non-compatible
D4. Contaminated waste from animals	☐ Compatible ☐ Non-compatible
D5. Sharps	☐ Compatible ☐ Non-compatible
D6. Other: _____ *Please refer to R. 61-105 for further definition of the infectious waste categories and prescribed infectious waste management requirements.*	☐ Compatible ☐ Non-compatible
D7. What waste characteristics present the greatest challenge to the proposed treatment process?	☐ Organic materials ☐ Liquids ☐ Density/Compaction ☐ Other Characteristics – Specify: _____

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

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

E. MICROBIOLOGICAL TEST PROCEDURES

E1. Listed below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. Any proposed treatment method shall be capable of inactivating mycobacteria at a 6 Log_{10} reduction or greater. Bacterial spores shall be inactivated at a 4 Log10 reduction or greater. **Treatment methods utilizing heat and/or steam must test at least one representative from the Bacterial Spore Group. Treatment methods utilizing other means must test at least one representative from the Bacterial Spore Group and one representative from the Mycobacterial Group.** Current State and Territorial Association on Alternate Treatment Technologies (STAATT) recommendations should be followed unless otherwise directed or approved by SCDES.

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

Mycobacterial Group ☐ Mycobacterium terrae ☐ Mycobacterium phlei

Bacterial Spore Group ☐ G stearothermophilus (ATCC 7953 or 12980) ☐ B. subtilis (ATCC 19659) ☐ B. atrophaeus (ATCC 9372)

E2. Indicate the test protocol, results, and an explanation of any available data not supporting the reduction factors referenced above.

E3. How were the protocols and conditions selected?

Were the protocols used appropriate for microbiological indicators and conditions? ☐ Yes ☐ No

E4. What, if any, certifications or credentials does the testing lab currently hold?

E5. How was inactivation level determined?

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 ☐ Heat ☐ Slag ☐ Vapors or Fumes
☐ Ash ☐ Leachate ☐ Smoke ☐ Other, Specify:_____
☐ Chemical Residues ☐ Liquid ☐ Stack Emissions
☐ Dust ☐ Odor ☐ Steam

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 U.S. EPA-listed hazardous wastes (40 CFR Part 261), biohazardous, etc.? ☐ Yes ☐ No

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? Specify.

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 infectious waste from this process be disposed of (i.e., landfill, incineration, recycled, etc.)? Specify.

H. OCCUPATIONAL HAZARDS

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

H2. What hazard abatement/reduction strategies will be used 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?

I2. What are the consequences if these factors are not met?

I3. Explain the ease and/or difficulty of operation of the infectious waste treatment system.

I4. What type of ongoing maintenance is required in the operation of the treatment system?

Is the maintenance manual attached? ☐ Yes ☐ No

I5. What emergency measures would be required in the event of a malfunction?

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?	Amount:
I8. Is there a minimum amount of waste per cycle to maintain effectiveness? ☐ Yes ☐ No	(If Yes) Amount:
I9. How long is a cycle?	Specify:

I10. Is a cycle batch or continuous? ☐ Yes ☐ No

J. CHEMICAL TREATMENT PROCESS

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

a. What is the name of the active ingredient?	Specify:
b. What concentrations must be used and maintained?	Specify:
c. At what pH is the chemical agent active?	Specify:
d. What is the necessary contact time?	Specify:
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)?	Specify:

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 infectious waste?	Specify:
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.	☐ Yes ☐ No
J4. What health and safety hazards may be associated with the chemical (present and long-term)?	MSDS attached? ☐ Yes ☐ No
J5. Is the chemical agent registered for this specific use with the U.S. Environmental Protection Agency (EPA) Pesticide Registration Division? If Yes, provide the EPA Registration Number and a copy of the EPA-approved label instructions for use.	☐ Yes ☐ No EPA Registration Number:
J6. Is the spent chemical agent classified as a hazardous waste by EPA (40 CFR Part 261) or by other state criteria? If Yes, specify whether by EPA or by which state(s). _____	☐ Yes ☐ No
J7. Is an environmental impact study for the chemical agent available? If Yes, attach a copy of this information.	☐ Yes ☐ No

K. QUALITY ASSURANCE AND VERIFICATION OF MICROBIAL INACTIVATION

K1. How is the quality assurance of the treatment process 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? 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
Tune Indicator:	☐ Visual Only	☐ Continuous	☐ Both
Chemical Concentration Indicator:	☐ Visual Only	☐ Continuous	☐ Both
Other	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 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?

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? Specify and provide.

L. POST-TREATMENT RESIDUE DISPOSAL, RECLAMATION OR RECYCLING

L1. How will the treated infectious wastes from this process be disposed of?	☐ Buried in an Approved Landfill	☐ Incinerated	☐ 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 infectious waste treatment and disposal methods?

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

N. OTHER RELEVANT INFORMATION AND COMMENTS

N1. All approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy must be included. Any approvals that included special conditions or concerns that needed resolution before approval should be included.

N2. All safety, competency or training requirements for the users/operators, etc. also must be included.

O. 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 SCDES with all results of all studies conducted by or for any state, company, agency or country, or any other person as defined by R. 61-105, and all results of all studies 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 infectious waste management systems to be operated in this state for infectious 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 SCDES review. Any and all changes in the system and related equipment after this application submittal and SCDES review and authorization to operate must be submitted in writing prior to use.

The Agency's permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy infectious waste will be reviewed by SCDES periodically to ensure specifically authorized infectious waste technology systems meet currently accepted standards for infectious waste management. SCDES 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, SCDES may have additional questions and require submissions of data and other information deemed necessary regarding this or related infectious 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 SCDES to deny or rescind authorization to operate if SCDES 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 and Title of Certifying Person (Corporate Officer):		
Signature of Certifying Person (Corporate Officer):	Date:	
Name and Title of Person Completing Application:		
Name of Vendor (Company):	Telephone:	
Name of Division:	Fax:	
E-mail:		
Address:		
City:	State:	Zip:

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Complete the following questionnaire and return it along with the application. Please print legibly or type your response. Use additional paper if necessary. Reference with the related section and number(s).

SECTION A

Al. Check best answer.

A2. Check best answer.

A3. Check Yes or No. If Yes, list states that have issued a decision and submit copies of approvals/disapprovals.

A4. Check Yes or No. If Yes, give details of violation(s).

A5. Check Yes or No. If Yes, give details of injuries or disease transmission.

A6. Check Yes or No.

A7. Check Yes or No. Give information about which SCDES programs were consulted and information given.

SECTION B

B1. Check Yes or No. If No, specify.

SECTION C

C1. Check best answer(s).

SECTION D

D1.-D6. Check best answer for each type of waste.

D7. Check the best answer(s).

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

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

SECTION E

E1. Check on the line next to each organism tested.

E2. Give information about protocols and data for above referenced microbiological testing.

E3. Indicated how the protocols and conditions were selected.

E4. Give information about the lab(s) that did the above referenced microbiological testing.

E5. Give information about inactivation in the above referenced microbiological testing.

SECTION F

F1. Check all answers that apply.

F2. Give information about control of discharges for each item checked in F1.

F3. Give information about determination that there would be no discharges.

F4. Check Yes or No. If Yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

SECTION G

G1. Give information about negative effects on the environment.

G2. Give information about negative effects of a malfunction of the process.

G3. Give information about liquid waste discharge.

G4. Give information about waste residues.

G5. Give information about waste disposal.

SECTION H

H1. Give information about potential occupational hazards.

H2. Give information about potential occupational hazard reduction strategies.

H3. Give information about operator training.

SECTION I

I1. Give information about factors critical to the process (e.g., time, temperature, pressure, waste density).

I2. Give information about consequences if factors critical to the process are not met.

I3. Is the system easy or difficult to operate? Why?

I4. Give information about ongoing maintenance requirements. Check Yes or No.

I5. Give information about emergency measures in the event of a malfunction.

I6. Give information about how emergency measures are communicated in writing.

I7. Give information about maximum weight or volume capacity per cycle.

I8. Give information about cycle length.

SECTION J

J1. Give specific information about any chemicals used for inactivation during the treatment process.

J2. How long can the chemical be useful or active?

J3. Are there studies available about duration of use?

J4. Please list hazards.

J5. Is the chemical a registered pesticide?

J6. Is the chemical a hazardous waste once used for its intended purpose?

J7. Has an environmental impact study been completed?

SECTION K

K1. Give information about quality assurance of the treatment process.

K2. Give information about recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system (e.g., per number of runs or batches, per time period).

K3. Give information about other indicators, integrators, or monitoring devices that would be used to show that the treatment unit or process was functioning properly.

K4. Check all that apply.

K5. Give information about correlation of the process with biological indicators.

K6. Give information about the process monitor calibration schedule, and its frequency of calibration.

K7. Give information about the process monitor's interface with the system's operations.

K8. Give information about prevention of operator over-ride of the process before treatment is adequately affected.

K9. Give information about failure mode and effect analyses that have been performed on the treatment system.

SECTION L

L1. Check all that apply.

L2. How and through what vendors will the wastes be recycled?

L3. Give information about recycled percentage and disposal of non-recycled waste.

SECTION M

M1. Check Yes or No. If Yes, specify and provide results of that analysis.

M2. Check Yes or No. If Yes, specify and provide results of that analysis.

M3. Give information about how this treatment technology improves on existing infectious waste treatment and disposal methods.

M4. Give information about the potential of this proposed technology for waste volume reduction.

SECTION N

N1. Provide all approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy, especially approvals that included special conditions or concerns that needed resolution before approval.

N2. Provide all safety, competency or training requirements for the users/operators, etc.

SECTION O

Print or Type items 1-4.

1. Name of SYSTEM/EQUIPMENT indicates the name of the system and/or equipment submitted for consideration.
2. Model Number indicates the model number of the system and/or equipment submitted for consideration.
3. Name of certifying person indicates the corporate officer responsible for the application and its accuracy.
4. Title is the company title of the certifying person.
5. Space for the signature of the certifying person (must be an original signature).

Print or Type items 6-15.

6. This should be date application is finalized.
7. The name of person completing application may or may not be the same as the certifying person.
8. Provide the company title of person completing application.
9. Provide the legal name of company selling the technology submitted for consideration (as registered with the Secretary of State of South Carolina).
10. Provide the telephone number (including area code and extension, if applicable) of company selling the technology submitted for consideration.
11. Provide the name of division of company selling the technology submitted for consideration.
12. Provide the fax number of company selling the technology submitted for consideration.
13. Provide the address of company selling the technology submitted for consideration.
14. E-mail is the electronic mail address of the person to whom correspondence should be addressed.
15. Include the name of the city, state and zip code of the company selling the technology submitted for consideration.