Petition for Evaluation and Approval of Regulated Medical Waste Treatment Technology

PART A: GENERAL INFORMATION

Company Information

Company Name: _____
Mailing Address: _____
City, State, Zip: _____

Contact Person: _____
Contact Phone: _____
Contact Title: _____
Contact E-mail: _____

Device Trade Name: _____
Model Number: _____

CERTIFCATION

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system or those persons directly responsible for gathering the information, the information submitted is to the best of my knowledge and belief true, accurate, and complete.

SIGNATURE: _____ DATE: _____

NAME: _____

TITLE: _____

Note: The review and assessment process will not commence until all information required is submitted by the petitioner and received by the Department.

EVALUATION OF MEDICAL WASTE TREATMENT TECHNOLOGY
INFORMATION REQUEST FORM

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

A. GENERAL

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

☐ Onsite ☐ 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 alternative 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.

_____

B. LEVEL OF TREATMENT

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

Demonstrate effective microbial and bacterial inactivation at a 6 Log_{10} reduction or greater reduction for the microorganisms and spores listed in 9VAC20-121-250.C and D through validation testing that meets the requirements of 9VAC20-121-260.

☐ Yes ☐ No

If no, specify where the requirement 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. Check all that apply.

- ☐ Chemical
- ☐ Encapsulation
- ☐ Grinder
- ☐ Hammermill
- ☐ Heat
- ☐ Irradiation
- ☐ Mechanical
- ☐ Microwave
- ☐ Plasma/Gasification
- ☐ Radiowave
- ☐ Shredder
- ☐ Other treatment process, please list: _____

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

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

Types 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. Human/Animal anatomical waste, tissues, and body fluids	☐	☐
D4. Contaminated waste from animals	☐	☐
D5. Sharps	☐	☐
D6. Prion waste	☐	☐
D7. Toxins or toxin waste solutions	☐	☐
D8. Solidified liquids	☐	☐

Please refer to the Regulated Medical Waste Management Regulations (9 VAC 20-121) for further definition of the medical waste categories and prescribed medical waste management requirements.

D6. What waste characteristics present the most challenge to the proposed treatment process?

- ☐ Organic materials
- ☐ Liquids
- ☐ Density/compaction
- ☐ Other characteristics (Specify) _____

D7. Describe by composition (i.e., material and percentage) those medical wastes that would provide the most challenge to the proposed technology. Why?

_____

E. BY-PRODUCTS OF THE TREATMENT PROCESS

E1. Please indicate all by-products which may be generated as a result of this alternative treatment technology and how each will be controlled and disposed.

Residue/By-Product	Control Mechanism and Ultimate Disposition
☐ Air Emissions	
☐ Ash or Slag	
☐ Dust	
☐ Heat	
☐ Liquid	
☐ Odor	
☐ Slag	
☐ Smoke	
☐ Steam	
☐ Vapors or Fumes	

☐ Other (Specify): _____

E2. Are any of these by-products toxic, biohazardous, etc.? ☐ Yes ☐ No

If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

_____

E3. If there are no waste residues or by-products, how was this determined?

_____

F. MICROBIOLOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, viruses, and mycobacteria at a 6 Log_{10} reduction or greater. A representative from each microbial group is required for testing.

F1. 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 data to support 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.

Vegetative Bacteria	**Parasites**
☐ Staphylococcus aureus (ATCC 6538)	☐ Cryptosporidium spp. Oocysts
☐ Pseudomonas aeruginosa (ATCC 15442)	☐ Giardia spp. Cysts
Fungi	**Mycobacteria**
☐ Candida albicans (ATCC 18804)	☐ Mycobacterium terrae
☐ Penicillium chrysogenum (ATCC 24791)	☐ Mycobacterium phlei
☐ Aspergillus niger	☐ Mycobacterium bovis(BCG)(ATCC 35743)
Viruses	**Bacterial Spores**
☐ Polio 2 or Polio 3	☐ B. stearothermophilus (ATCC 7953)
☐ MS-2 Bacteriophage (ATCC 15597-Bl)	☐ B. subtilis (ATCC 19659)

☐ Other (Specify): _____

F2. Were the results certified by an independent, public health or certified testing laboratory?
☐ No ☐ Yes

If yes, indicate the name, address, telephone number of the certifying laboratory: _____
Attach test protocol and results.

G. CHEMICAL INACTIVATION TREATMENT PROCESSES

If the treatment process involves chemical inactivation, provide the following information specific to the treatment process.

G1. a) What is the name of the active ingredients? _____
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: _____

G2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?
_____

G3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use?
☐ No ☐ Yes - If yes, please attach a copy of the study and test results.

G4. What health and safety hazards may be associated with the chemical (present and long-term)?
_____
MSDS Attached? ☐ No ☐ Yes

G5. Is the chemical agent registered for this specific use with the Environmental Protection Agency (EPA) Pesticide Registration Division?
☐ No ☐ Yes

If yes, provide the EPA registration number: _____

G6. Is the spent chemical agent classified as a hazardous waste by U.S. EPA (40 CFR Part 261) or by other state criteria?
☐ No ☐ Yes

If yes, specify whether by USEPA or which state: _____

G7. Is an environmental impact study for the chemical agent available?
☐ No ☐ Yes - If yes, attach a copy of this information.

H. ENVIRONMENTAL EFFECTS ON THE TREATMENT PROCESS

H1. Can positive or negative effects on the environment be anticipated from the use and/or disposal of the treated waste from the treatment process?
☐ No ☐ Yes

If yes, specify: _____

H2. What environmental, occupational, and/or public hazards would be associated with a malfunction of the treatment process?

_____

H3. If the treatment process includes the use of water, steam, or other liquids; how will this waste discharge be handled (i.e., sewer, recycle, etc.)?

_____

H4. How will the treated waste from this process be disposed of (i.e., landfill, incineration, recycle, etc.)?

_____

H5. Are the by-products identified as a hazardous waste?
☐ No ☐ Yes – If yes, complete item M1

I. CRITICAL FACTORS OF 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 medical waste treatment system.

_____

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

_____

Maintenance Manual Attached? ☐ No ☐ Yes

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

_____

I6. Are these measures addressed in an emergency plan or in the operations protocol?
☐ No ☐ Yes - If yes, attach a copy

I7. What is the maximum amount of waste to be treated by this process per cycle? _____ Specify Units

I8. How long is a cycle?_____ Specify Units

J. QUALITY ASSURANCE AND VERIFICATION OF ADEQUATE TREATMENT

J1. How is the quality assurance of the treatment process addressed?

_____

J2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system? _____

J3. Other than the biological indicators listed in Section F, 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.)

_____

J4. How is it determined that the processed waste has received proper treatment?
(Check the appropriate item.)

Indicator Parameter	Operation Setting	Recording Method
☐ Temperature:		Specify
☐ Pressure:		Specify
☐ Time:		Specify
☐ Chemical Concentration		Specify

☐ Other (Please specify): _____

J5. Have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process?

_____

J6. Is there a process monitor calibration schedule established, and at what frequency is calibration performed?

_____

J7. Are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.

_____

J8. Are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately effected? Explain.

_____

K. POST TREATMENT RECYCLING

K1. Has a strategy been developed for the recycling of any part of the treated waste?
☐ No ☐ Yes

If yes, please include additional information regarding the strategy.

_____

L. COMPLIANCE WITH MEDICAL WASTE REGULATIONS

L1. Does your treatment technology meet the requirements of the Regulated Medical Waste Management Regulations (9VAC20-121) for medical waste decontamination and disposal?
☐ No ☐ Yes

L2. Which of the following categories of medical waste will be effectively treated by your system? (Check all that apply.)

- ☐ Animal carcasses or body parts
- ☐ Animal bedding and related wastes
- ☐ Category A wastes
- ☐ Chemo and/or Radioactive Wastes (transfer only)
- ☐ Cultures and Stocks
- ☐ Human blood and body fluids
- ☐ Human pathological and anatomical waste
- ☐ Other Wastes, please list: _____
- ☐ Mixed RMW and solid waste
- ☐ Non-hazardous Pharmaceuticals
- ☐ Prion waste
- ☐ Residues
- ☐ Sharps
- ☐ Solidified liquids
- ☐ Toxins or toxin waste solutions

M. INTERAGENCY COORDINATION

M1. Have you inquired from the State's medical waste permit coordinator as to whether any other permits are required?
☐ No ☐ Yes - If yes, please enclose the response and requirements with your application.

NOTE: Local governments may require permits.

N. POTENTIAL ENVIRONMENTAL BENEFITS

N1. Has an energy analysis been conducted on the proposed technology?
☐ No ☐ Yes

If yes, specify and provide results of that analysis. _____

N2. Has an economic analysis been performed on the proposed technology?
☐ No ☐ Yes

If yes, specify and provide results of that analysis. _____

N3. How does this treatment technology improve on existing medical waste treatment and disposal methods?

_____

N4. What is the potential of this proposed technology for:

Waste volume reduction? _____

Recycling? _____

O. OTHER RELEVANT INFORMATION AND COMMENTS

(Approvals received from other states, operator safety, competency or training requirements for the users/operators, etc.)

_____

PART B: ATTACHMENTS

The general information contained in Part A and this checklist are a required part of the petition package. These assist the petitioner in submitting the petition and the Department in its review, and they are supplemental to the required documents listed below. The complete petition package consists of a completed Part A form, this Part B checklist, all information required by 9VAC20-121-250 of the Regulated Medical Waste Management Regulations, the documents listed below (as applicable), and any other supportive data or information the petitioner wishes to be considered.

- ☐ DEQ Form RMWTP-01
- ☐ Detailed description of alternate treatment technology, including operating procedures and conditions, parametric controls, description of waste residues and by-products.
- ☐ Operations / Equipment manual
- ☐ Equipment specifications
- ☐ Maintenance Manual
- ☐ Microbial and bacterial inactivation testing demonstration including protocols utilized
- ☐ Chemical Management Plan with Material Safety Data Sheets
- ☐ Environmental Protection Agency pesticide registration documents, as applicable
- ☐ Occupational safety and health assurance