PETITION FOR EVALUATION AND APPROVAL OF
REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY
PART A: GENERAL INFORMATION

Name of Company			
Name of Petitioner (Must be an individual(s) Name)			
Trade Name of Device		Model Number	
Petitioner Address			
City	State	ZIP	Telephone Number

Department Use Only

Date Application and Questionnaire Received	Date Complete

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?

Inactivation of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater, and B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater.

☐ 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.

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

☐ Other(specify)_____

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 biological	☐	☐
D2. Liquid human and animal waste including blood and blood products and body fluids	☐	☐
D3. Human anatomical waste, tissues, and body fluids	☐	☐
D4. Contaminated waste from animals	☐	☐
D5. Sharps	☐	☐

Please refer to the Regulated Medical Waste Management Regulations (9 VAC 20-120) 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.

☐ Air Emissions ☐ Heat ☐ Slag ☐ Vapors or Fumes
☐ Ash ☐ Liquid ☐ Smoke
☐ Dust ☐ Odor ☐ Steam
☐ Other (Specify) _____

E2. If any of the above by-products are indicated, how will they be controlled?

_____

E3. If there are no by-products indicated, how was this determined?

_____

E4. Are any of these by-products toxic, biohazardous, etc.?
☐ No ☐ Yes - If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

_____

F. MICROBIALOGICAL 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.

Fl. 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
☐ 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-Bl)

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)

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 and attach test protocol and results.

_____

G. CHEMICAL INACTIVATION TREATMENT PROCESSES

G1. If the treatment involves the use of chemical inactivation:

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?

_____

I8. How long is a cycle?

_____

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.)

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: _____

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 (9 VAC 20-120) for medical waste decontamination and disposal?

☐ No ☐ Yes

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

Types of Waste	NO	YES
a) Cultures and Stocks:	☐	☐
b) Blood and Blood Products and Body Fluids	☐	☐
c) Human Anatomical Waste, Human Tissues, and Body Fluids	☐	☐
d) Sharps	☐	☐
e) Contaminated Animal Waste	☐	☐

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.)

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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 the documents listed below, and any other supportive data or information the petitioner wishes to be considered.

☐ Petitioner's submittal certification

☐ Quality Assurance and Quality Control Report

☐ Microbiological testing report

☐ Material Safety Data Sheets

☐ Environmental Protection Agency pesticide registration documents

☐ Maintenance manual

☐ Emergency operations manual

☐ Operations manual

☐ Design plans and specification