Alternative Medical Waste Treatment Technology

This approval process is for treatment of medical waste in a manner other than by incineration, steam sterilization, or by approved discharge to a public sewer.

Applicant Information

Company Name:		
Applicant Name:		
Street Address:		
City:	State:	Zip Code:
Email:		
Telephone:	Fax:	

OPERATIONS

1. Briefly describe the technology.

2. Check the appropriate categories to best describe the methods used by the proposed technology.

☐ Chemical	☐ Shredding
☐ Heat	☐ Steam
☐ Microwave	☐ Other (attach description)
☐ Plasma Arc	
☐ Pyrolysis	

3. Provide the equipment model and serial number, specifications and operations manual. If the equipment has more than one model, approval must be obtained for each.

Brand:
Model:
Serial Number:

4. Submit photographs and/or schematic drawings of the treatment system design.

5. Note the maximum amount of waste to be treated by this process per cycle and the length of the cycle, or feed rate for a constant feed system.

Related capacity/cycle:
Length of cycle/Feed rate:

6. Note any physical or chemical conditions which must be maintained in order to ensure the effectiveness of the treatment process.

7. Detail the consequences of these factors not being met.

8. Indicate compatible and non-compatible waste types for treatment using the proposed system.

☐Yes ☐No Cultures & stocks of infectious agents
☐Yes ☐No Human surgery or autopsy specimens
☐Yes ☐No Recognizable fluid blood, blood products, containers, or equipment containing blood
☐Yes ☐No Needles, syringes, pipettes, other contaminated broken glass
☐Yes ☐No Pharmaceutical waste
☐Yes ☐No Human/animal specimen cultures
☐Yes ☐No Wastes from the production of bacteria viruses, spores, discarded live and attenuated vaccines (animal or human)
☐Yes ☐No Animal parts, tissues, fluids, carcasses
☐Yes ☐No Excretions, exudates, secretions from humans or animals requiring isolation
☐Yes ☐No Metal instruments or components
☐Yes ☐No Trace chemotherapy waste
☐Yes ☐No Large amounts of liquid, such as suction canisters

9. Describe the technology's relative suitability for use at the waste's point of origin and/or at an off-site treatment facility as applicable.

10. For alternative treatment technology that depends on chemical disinfection include the following information:

Name of the disinfectant and the active ingredient:
Concentration required to be used and maintained:
pH:
Contact time:
Recommended compatibility of specific materials and surfaces:
MSDS:

11. Indicate the residual concentration of the disinfectant after it has been exposed to air and contaminated medical waste.

12. Note whether the disinfectant is classified as a hazardous waste under the Federal Resource Conservation and Recovery Act (RCRA) or the California Hazardous Waste Control Act. Is the treated medical waste classified as such?

13. Describe any special training and/or knowledge necessary to operate the treatment system and how this information is provided to users of the technology.

HEALTH AND SAFETY

14. List acute and/or chronic health and/or safety hazards associated with any operation of the treatment technology.

15. List acute and/or chronic health and/or safety hazards associated with use of the chemicals used in the treatment technology. Provide a MSDS.

MAINTENANCE

16. Describe maintenance required to operate the treatment system on an ongoing basis. Provide a projected downtime, as a proportion of operating time, necessary to complete these activities.

17. Provide the calibration schedule and/or protocol necessary to ensure that all treatment parameters are met. If filtration is used, describe the process for routine testing and safe removal/installation.

QUALITY ASSURANCE/QUALITY CONTROL

18. Describe the quality assurance/quality control process used to determine that the waste has been properly and adequately treated. Include information regarding all applicable physical or chemical variables such as time, temperature, pH or pressure.

19. Also list, and describe the use of, any indicators, integrators or other monitoring devices that would be used for this purpose. Note the recommended frequency for their use.

ENVIRONMENTAL EFFECTS

20. Describe appropriate disposal options for wastes treated using this technology.

21. Describe how byproducts will be disposed of and any environmental effects mitigated.

22. Indicate all byproducts that may be generated as a result of this alternative treatment technology.

☐ Air emissions	☐ Heat	☐ Smoke
☐ Ash (include metals)	☐ Liquids	☐ Steam
☐ Dust	☐ Odor	☐ Vapor
☐ Fumes	☐ Slag	☐ Other solids

23. Describe any effects on the environment anticipated from the disposal of waste treated using this alternative treatment technology. This includes, but is not limited to emissions to the air, water or land.

24. Describe environmental, occupational or public health hazards associated with any potential malfunction of the treatment process or equipment. Include the emergency plan or operational protocol addressing these measures. Describe emergency measures required in the event of such a malfunction. Indicate any training and procedures provided to the users of the treatment technology to lessen the risk of these hazards.

25. If the treatment process includes the use of water, steam or other liquids, describe how liquid waste discharge is to be neutralized and removed (e.g. sewer, recycle, etc.).

TESTING AND OTHER REQUIREMENTS

26. Any proposed treatment method shall be capable of destroying pathogenic microorganisms, including bacteria, fungi or yeasts, bacterial spores and viruses, as well as bacteria which are resistant to heat, antibiotics and disinfectants. The criteria include a 4 Log_{10} reduction in the level of *Bacillus* spores. Other test organisms may be required if deemed necessary by the Department. The testing must provide data which demonstrate that the proposed technology achieves these criteria.

27. If testing has not yet been completed, the proposed testing protocol and the testing laboratory must be approved by the Department.

28. Chemical disinfectants must be properly registered with the United States Environmental Protection Agency (EPA). If not currently registered indicate the status of the application.

29. Chemical disinfectants must be properly registered with the California Department of Pesticide Regulation (DPR), Pesticide Registration Branch prior to use in California. Provide the DPR registration number, and include a sample product label in the application package. If not currently registered indicate the status of the application.

30. It is the responsibility of the applicant to obtain any other required regulatory agency's approval(s) prior to applying with the Department.

31. Once a technology is approved, some systems may be able to use parametric monitoring in place of efficacy testing performed with biological indicators. Such monitoring would need approval by the Department and would be periodically inspected at the treatment facility to ensure that the parameters (time, pressure, temperature, chemical concentration, etc.) were being properly maintained.

Mailing Instructions

For an application to be deemed complete for review, submit this completed application form, an application developed per the attached guidance and a check in the amount of $2,500 made payable to the Medical Waste Management Fund. All submittals should be mailed to:

Medical Waste Management Program
California Department of Public Health
MS 7405, IMS K-2
P.O. Box 997377
Sacramento, CA
95899-7377

Certification

I certify under penalty of perjury that the information contained in this application is true and accurate to the best of my knowledge and belief.

Name:	Title:
Signature:	Date:

Note: The review process will not commence until the complete application and fees have been received. Provide complete information on the following items. Include additional supporting data, as needed.

For Department use only

Date Application package received _____
Date Check received by Department _____
Date review completed _____

Frequently Asked Questions on Efficacy Testing and Reporting

What is a Notice of Contract Laboratory?

A Notice of Contract Laboratory includes:

1. The name of the laboratory;
2. The mailing (and, if different, physical) address of the laboratory;
3. The name of the Study Director and staff associated with the application;
4. References and Curricula Vitae of Study Director and all staff associated with the conduct of the study;
5. Contact information such as any voice and facsimile telephone numbers, electronic mail or Internet addresses that would facilitate Department communication with the laboratory;
6. A Study Director's Statement providing proof of certification or accreditation by an independent certifying body such as International Organization of Standards (ISO), Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), College of American Pathologists (CAP) or equivalent as demonstrated to the Department
7. A release from the applicant allowing the laboratory to provide all information it may obtain relating to the alternative treatment technology directly to the Department

What is a laboratory testing protocol?

1. A protocol is a set of laboratory procedures taken from generally accepted technical references, for example the Official Methods, Association of Official Analytical Chemists (AOAP).

2. The purpose of the protocol is to demonstrate that the employed analysis will demonstrate that the alternative medical waste treatment technology will destroy pathogenic organisms when used according to the manufacturer's instructions.

3. An applicant's internally developed procedures need to be justified as to their necessity, validity, and reliability by the testing laboratory.

What must be included in the protocol?

1. An approved protocol will include a full description of all procedures to be performed, from the beginning to the end of the test, and be written at a level of detail that eliminates choice and vagueness in the execution of the study.

2. A completed protocol should, at a minimum, incorporate the following attributes:
    a) An experimental design that faithfully portrays the function of the alternative technology
    b) Is free of confounding variables
    c) Satisfies the following design requirements when applicable to the technology:
        i) Testing that is carried out with actual treatment systems, not with scaled-down simulations

ii) Efficacy tests that are conducted with a minimum of three surrogate test loads
iii) Surrogate test loads that are equal to the systems' treatment capacities.

What kind of documentation is required?

1. A full description of all procedures, from the beginning to the end of the testing, *as performed*.

2. Traceability of each step to Association of Official Analytical Chemists (AOAC), other standard reference works accepted for use in the testing by the Department, or to Standard Operating Procedures (SOP) maintained by the laboratory in accordance with its certification or accreditation.

3. The study's Quality Assurance Report pursuant to the Good Laboratory Practice or quality assurance standards acceptable to the Department.

4. Justification and demonstration that biological indicators (i.e., ampules, strips) are not artificially affected by the testing process.

5. Justification and demonstration of inoculum traceability, purity, viability and concentration.

6. Dilution and neutralization methods that do not affect microorganism viability.

7. Justification and demonstration that microorganism recovery methodologies are statistically correct with respect to factors including, but not limited to, sample collection, number of samples per test, number of colony forming units/plate, and are not responsible for the destruction of the pathogen.

8. Justification and demonstration that appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times) are used.

9. Identification of all organisms used in testing by genus and species name, and by American Type Culture Collection Accession number.

10. Full description of all procedures used in growing and maintaining cultures, including any applicable test inocula.

What other features must be included in the testing records?

Testing records should confirm that the analysis incorporated the following features:

1. Test loads that are equal to the systems treatment capacities.

2. Waste that constitute a homogeneous sample.

3. Use of actual medical waste to be processed by the technology for its proposed use.

4. Waste compositions should mimic the maximum volume and density (e.g. bio load, specific heat, electrical conductivity), to be used in the treatment process.

5. Testing under conditions comparable to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load weight, density, volume, organic soil).

6. Whenever test organisms will be contained in tubes or ampules, conditions within the specimen containers must be equivalent to those of the treated waste in general.

What should I include in my Final Laboratory Report?

An acceptable Final Laboratory Report will include:

1. A full description of all procedures, from the beginning to the end of the testing, *as performed*.

2. Documentation and justification of any changes in procedure due to operational necessity summarized in a table.

3. Traceability to Association of Official Analytical Chemists (AOAC), other standard reference works acceptable to the Department, or to Standard Operating Procedures (SOP) maintained by the laboratory in accordance with its certification or accreditation.

4. Inclusive results of testing, including all data obtained, even those data are not in support of the technology's efficacy claim.

5. Upon Departmental request, the submittal of the study's Quality Assurance Report pursuant to the Good Laboratory Practice Statement. This request may be made up to three (3) years after the Department's has approved the alternative medical waste treatment technology for use in California.