Guidelines for Approval of Alternative Regulated Medical Waste Treatment Technologies

Manufacturers seeking approval for alternative treatment technologies are required to obtain approval prior to using the technology in the field as outlined below. Once the technology is approved, the **users** of the technology must confirm, as outlined in a document entitled "Installation Approval Guidelines for Facilities that use Alternative Regulated Medical Waste Treatment Systems," that operational parameters, validation testing, and book keeping requirements are completed prior to start-up of an approved alternative treatment system. These guidelines are designed to assist in the preparation of the packages that will be submitted for review and should be used in conjunction with Public Health Law Section 1389-bb through 1389-ff and 10NYCRR Part 70-4 and 70-5.

System Approval for Manufacturers of Alternative Regulated Medical Waste Treatment Technologies

I. Overview of Technology and Operation Parameters
II. Efficacy Testing Protocol and Results
III. Renewal
IV. Efficacy Testing Setup

I. Overview of Technology and Operation Parameters

The proposed alternative technology needs to be described in detail and operation parameters established. This section needs to include:

Manufacturer Information

- Manufacturer's name and address, CEO, and website, if any
- Contact Person – list name, address, e-mail, and telephone/fax number
- Information pertaining to the location of the test site (on site at the point of generation or offsite)

System Information

- Name of the technology
- Model Number
- Schematics/diagrams/photographs of the system

Description of Treatment Technology

- Method used by the system in the treatment of medical waste – indicate chemical, heat (Microwave, Plasma Arc, Pyrolysis etc.) or ionization
- Treatment capacity (pounds or gallons per cycle)
- Duration of treatment
- If heat, indicate temperature range for effective treatment
- If chemical, submit EPA approval and NYS Department of Environmental Conservation registration.

Description of Operational Parameters

- Detailed description of the operating procedures (System's Operation Manual)
- Indicate mechanical action (encapsulation, grinder, shredder etc.)
- Indicate if operating parameters are automatically and continuously monitored throughout the cycle
- Identify whether complete treatment occurs within the treatment vessel or device
- Indicate if mobile unit
- Indicate how process or exhaust air emissions issues will be addressed
- Types of waste to be processed (indicate if pathological waste will be treated)
- Describe operator safety mechanisms and controls integral to the system or required prior to operation (e.g., automated loading, lockout controls, HEPA or Charcoal filters, personal protective clothing, etc.)
- Describe the finished product (e.g., shredder fluff, compressed or congealed waste, etc.)

Additional Information

- List other state approvals
- (included below in first bullet)

II. Efficacy Testing Protocol

In order to verify that medical waste is appropriately treated and rendered unrecognizable, thereby eliminating the threat to public health and safety, efficacy testing must be performed using the system and operation parameters described above (in Section I). The procedure must conform to recognized scientific principles. Test protocols must be approved by the Program PRIOR to initiation of efficacy tests to ensure that parameters established in the protocols will provide effective treatment of medical waste. Once the procedure is approved, the manufacturer can initiate testing and submit results for review. Efficacy testing protocols must:

- Identify the independent laboratory performing testing, including name, address, telephone number, contact information, and written verification from that laboratory indicating that testing will be performed using EPA Good Laboratory Practice Standards.
- Be performed on the full scale-working model of the system described in Section I. and approval will be limited to specific models of the system. Bench top studies are not acceptable.
- Be performed using surrogate loads of non-infectious waste that reflects the typical composition of waste generated by a facility and presents the worse case scenario for treatment.
- Be performed on test loads consisting of at least 5% of organic material (i.e., blood, cultures, media etc) for mixed batches of medical waste, and a higher percentage for test loads containing only pathological waste.

- Include appropriate biological indicators and controls. Surrogate waste loads need to be seeded with known concentrations of *Geobacillus stearothermophilus* or *Bacillus atrophaeu*s (for chemical systems). It must be demonstrated that the system is capable of causing a 4 $\log_{10}$ reduction in the concentration of *Geobacillus stearothermophilus* or *Bacillus atrophaeu*s spores. Be sure to provide confirmation

that the starting concentration of viable microorganisms used to seed simulated medical waste is sufficient to arrive at an appropriate final initial concentration.

- Include laboratory, field, and untreated controls (see Section IV. Efficacy Testing Procedures below for description of controls).
- Include a description of how sample integrity will be maintained for shipment to the testing facility (insulated containers or temperature monitoring strips can be used to confirm adequate temperatures and specimen integrity)
- Include a record of temperatures at various intervals of testing
- Include a record of start up, residence and cool down (if applicable) time for each sample within the system
- Include data from at least 3 runs with a minimum of 3 samples per run

III. Renewal

System efficacy approvals in New York State are valid for a period of two years. Manufacturers are now required to submit biannual renewals to the Department in order to update manufacturer contact information delete inactive technologies and allow tracking of alterations that may affect an approved system's treatment capabilities. To renew, the manufacturer must:

- File with this Program no later than 180 days prior to the expiration of the existing approval
- Provide a list of all installations placed in New York State
- Notify this Program of any change or modification to the system that adversely affects the system's efficacy and could necessitate the submission of additional efficacy testing. Failure to notify the Program of any such changes or modifications will void renewal and prior approval.

IV. Efficacy Testing Procedures

To demonstrate effectiveness of the treatment, biological indicators must be properly used. Supporting documentation identifying biological indicator lot number, concentration and D-values must be supplied by the commercial manufacturer of the biological indicators proposed to be used. Indicators used in the test should include laboratory, field, and untreated controls. The information below describes an example of laboratory, field, and untreated controls used to demonstrate efficacy of a chemical method for treatment. The Regulated Medical Waste Program Coordinator can be contacted for additional guidance on use of biological indicators in efficacy testing.

- **LABORATORY CONTROLS**

Laboratory controls are used to determine the starting concentrations of the biological indicators. It is imperative that concentrations are equivalent to the concentrations established by the commercial supplier of the indicators. To process the controls, the independent laboratory performing testing retains a set of indicators to determine starting concentrations.

- **FIELD CONTROLS**

Field controls are used to determine if the shipment between the testing laboratory and the testing site has an effect on the viability of the indicators. To process the controls, the laboratory performing testing must send triplicate set of indicators to the

test site where they are placed into vials of buffered neutralizer to be returned to the testing laboratory – no processing of the organisms is performed. These are returned to the testing laboratory under refrigeration and overnight delivery.

- **NEUTRALIZER CONTROLS**

Neutralizer controls are used to determine if the neutralizer has any affect on the viability of the indicators and to determine if the chemical is neutralized. To process the controls, an aliquot of the chemical is removed at the beginning, middle, and end of the treatment process. The solutions are added to a set of indicators provided by the testing laboratory and returned to the testing laboratory under refrigeration and overnight delivery.

- **UNTREATED CONTROLS**

Untreated controls are used to establish a baseline concentration of indicators recovered after exposure to the mechanical aspects of processing the waste through the system. To process the controls, the indicators are processed through the system in the absence of the chemical (water is used) and the waste test load. These samples are placed in a neutralizer solution and returned to the testing laboratory under refrigeration and overnight delivery.

- **TEST SAMPLES**

Test sample controls are used to demonstrate that the treatment process properly inactivates the indicators. To process the controls, indicators obtained from the testing laboratory are added to the system and retrieved at the beginning, middle and end of the processing for a total of three indicators per run. This must be performed on three independent runs of the system for a total of 9 indicators. Upon recovery from the carrier, the indicators are placed in a neutralizer solution and returned to the testing laboratory under refrigeration and overnight delivery.

V. OTHER ISSUES

Load configuration, packing density, waste orientation and composition, type of packaging, moisture content, thermal properties and volume may all impact treatment and must be accounted for during the efficacy testing. Description of the test procedures, photo documentation and schematics of each load, and identification of sample locations within the test loads are critical to authenticating test procedures as they occur. It is also important that test results are reproducible and it is necessary to evaluate natural attenuation of samples as part of the test procedure.