



State of Ohio Environmental Protection Agency

STREET ADDRESS:

1800 WaterMark Drive  
Columbus, OH 43215-1099

MAILING ADDRESS:

P.O. Box 1049  
Columbus, OH 43216-1049

ENTERED DIRECTOR'S JOURNAL

TELE: (614) 644-3020 FAX: (614) 644-2329

SEP 16 98

OHIO E.P.A.

SEP 16 1998

RE: Approval of the STI Chem-Clav  
STI-2000CV  
Infectious Waste Treatment Technology

Mr. Randall McKee  
Sterile Technology Industries, Inc.  
STI Chem-Clav  
1155 Phoenixville Pk.  
Unit 105  
Park Valley Corp. Ctr.  
West Chester, PA 19380

I certify this to be a true and accurate copy of the  
official document as filed in the records of the Ohio  
Environmental Protection Agency.

By: Zona K. Clements Date 9-16-98

Dear Mr. McKee:

Pursuant to Section 3734.021 of the Revised Code, the Director of Ohio EPA has the authority to approve the use of alternative technologies for the treatment of infectious waste. The Ohio EPA expends considerable effort to be responsive to the needs of the community for an alternative method for the treatment of infectious wastes. It is in response to those needs for timely alternative treatment methods, yet to also fulfill the requirement to gather specific information regarding each treatment technology, that Ohio EPA has developed rules providing for or implemented the current alternative infectious waste treatment approval process. Ohio EPA's current approval process allows for either statewide or site-specific approval of an alternative infectious waste treatment technology based on the submission of data that demonstrates the successful achievement of the performance standard.

The request by Sterile Technology Industries, Inc. for statewide approval was submitted on January 22, 1996. The STI Chem-Clav, STI-2000CV operates on the principal of both chemical and steam inactivation of the microorganisms. Chemical relies on exposure of the surface area of the waste load to the chemical. Steam relies on penetration of the steam into the waste load. The grinding performed by this unit increases both the surface area of the waste load for exposure to the chemical and the penetration of the steam. Thus, inactivation of the microorganisms is achieved through a two-fold exposure of the waste load to: 1) a minimum time and concentration of a sodium hypochlorite solution and 2) a minimum exposure time and temperature to steam. The Sterile Technology Industries, Inc., STI Chem-Clav, STI-2000CV system operates for a minimum total treatment time of forty (40) minutes.

Infectious wastes, that have been properly packaged in accordance with Rule 3745-27-34 of the Ohio Administrative Code, are loaded onto the stainless steel feed conveyor. The entire feed conveyor is under negative pressure and the air is drawn through a HEPA filter. The infectious wastes are moved upward to the feed conveyor hopper and dropped onto the top of the primary shredder. A spray mixture of sodium hypochlorite (NaOCl) and water is applied to the containers of infectious wastes prior to being broken open by the primary shredder. A pneumatic ram applies pressure to the containers to push the containers to the primary shredder. The shredded materials fall through the transition chute where an additional amount of hypochlorite solution is sprayed on to the shredded waste. The shredded contents are next processed in a another shredder for further size reduction of the waste. The waste from the secondary shredder falls into the screw press hopper. The waste falls into the screw press where liquids are separated from the solids. The liquids drain back to the re-circulation tank where they are pumped back to the various sprayers and new sodium hypochlorite is applied to the re-circulated liquids. The re-circulation tank is equipped with baffles to screen out large particulates from the liquid as well as a line filter located before the hypochlorite injection site. Excess liquid accumulated in the reservoir is removed through an overflow

into a disposal system. The screw press employs a pneumatic system ram at the distant end to apply pressure to the screw. The resultant waste product exits the screw press in the form of a "press cake" material. The proportional pump maintains a minimum constant 2550 parts per million (ppm) Free Available Chlorine (FAC) within the system. The press cake material falls into the steam conveyor hopper where it is exposed to steam for a minimum of thirty minutes. The steam conveyor has multiple injection ports for low pressure (a maximum of 15 pounds per square inch [psi]) steam. The steam section maintains an operational temperature at a minimum of 205 degrees Fahrenheit.

Pursuant to Rule 3745-27-32 of the Ohio Administrative Code and based upon the submitted documents: 1) the "Evaluation of Infectious Waste Treatment Technology Information Request Form" and request for approval, submitted January 22, 1996; 2) microbiological testing submitted by BBI Clinical Laboratories, Inc., December 19, 1997 and all subsequent versions; 3) STI Chem-Clav, NEW, MODERN WASTE STERILIZATION SYSTEM FOR HOSPITALS & REGIONAL FACILITIES, Operation & Maintenance Manual, revised 12/1/95; and 4) the STI Chem-Clav, NEW, MODERN WASTE STERILIZATION SYSTEM FOR HOSPITALS & REGIONAL FACILITIES, Operation & Maintenance Manual, revised 5/8/97; the Sterile Technology Industries, Inc., STI Chem-Clav, STI-2000CV is approved statewide provided each statewide installation conforms with the following conditions:

1. Each STI Chem-Clav, STI-2000CV treatment unit shall be operated in accordance with Rule 3745-27-32 of the Ohio Administrative Code and utilizing the following parameters:
  - a. Only infectious wastes properly packaged in accordance with Rule 3745-27-34 of the Ohio Administrative Code are to be processed in the STI Chem-Clav, STI-2000CV.
  - b. The operator shall not place any waste onto the feed conveyor belt after the "ON-OFF" switch has been placed in the OFF position.
  - c. The shredding and dewatering tower (a grinding and chemical soak process phase) shall operate for a minimum of ten (10) minutes at the beginning of the treatment cycle.
  - d. The shredders, located in the shredding and dewatering tower, shall have a maximum screen opening of two and one-half (2 1/2) inches in diameter.
  - e. The steam process phase shall operate for a minimum of thirty (30) minutes at the end of the treatment cycle prior to the waste exiting the treatment unit.
  - f. The temperature of the re-circulated liquids shall be a minimum of 105 degrees Fahrenheit (F).
  - g. The maximum speed of the steam clav auger shall be one (1) revolution per minute (rpm).
  - h. The steam in the steam conveyor shall be a minimum of 205 degrees Fahrenheit (F).
  - i. Only concentrated (10-12.5%) sodium hypochlorite (NaOCl) diluted with a mixture of water and NaOCl from the re-circulation tank shall be used for the chemical treatment of the infectious waste in the treatment unit.
  - j. The concentrated (10-12.5%) sodium hypochlorite (NaOCl) shall be diluted with the re-circulation tank mixture at the top of the shredder / dewatering tower prior to the hopper sprayer outlet port.
  - k. Prior to operation of the treatment unit to treat infectious waste, the operator shall determine and document, in the daily log, the appropriate mixture of sodium hypochlorite to re-circulation tank liquid to maintain a minimum 2550 parts per million (ppm) Free Available Chlorine (FAC) at all times during the operation of the STI Chem-Clav, STI-2000CV to treat infectious wastes.
  - l. The operator shall re-calibrate the sodium hypochlorite to re-circulation tank liquid flow ratio, prior to continued use should any change in the following occur: 1) the sodium hypochlorite

- solution, 2) re-circulation tank liquid, 3) flow ratios, or the 4) operator
- m. The daily log shall be completed daily with all the required information and notation in the log shall be made if any of the following occurs: 1) operator change, 2) treatment unit shut-down or stopped, 3) treatment unit malfunction, or 4) sodium hypochlorite re-circulation tank liquid flow ratio re-calibration.
- n. The STI Chem-Clav shall be equipped with a permanent continuous recording device. The recording device shall continually monitor and produce the following information every two (2) minutes the treatment unit is used to treat infectious waste. The permanent continuous recording device shall produce a printout of, at a minimum, the following:
- date
  - time
  - temperature of the water in the re-circulation tank
  - temperature of the steam at the beginning of the steam clav section
  - temperature of the steam at the end of the steam clav section
  - the flow rate of the sodium hypochlorite and water solution
- o. The operator shall perform quality assurance spore testing as prescribed in Attachment B.
- p. The operator shall perform quality assurance testing for every forty (40) Machine Hours that the STI Chem-Clav, STI-2000CV is used for infectious waste treatment and record the results in the Quality Assurance log as prescribed in Attachment B.
- q. If the STI Chem-Clav, STI-2000CV fails any quality assurance testing, the operator shall cease to use the treatment unit to treat infectious waste until such time that the treatment unit is repaired or calibrated and passes a subsequent quality assurance test. Once the treatment unit demonstrates the achievement of the performance standard (following the failed quality assurance test), the operator shall continue to perform quality assurance testing every forty (40) Machine Hours. The results of all quality assurance testing shall be recorded in the Quality Assurance log as prescribed in Attachment B.
2. The operator, if applicable, shall develop and maintain in one area on the premises of the infectious waste treatment unit a Facility Management Plan (FMP) pursuant to Rule 3745-27-32 of the Administrative Code. The Plan shall also include the following information and documentation:
- a. A statement signed by each treatment unit operator certifying that training has been provided to them regarding the operation and maintenance of the STI Chem-Clav, STI-2000CV.
- b. Information specified in condition 4.
3. Upon request of the Ohio EPA, the operator of each unit shall perform quality control testing. This testing must demonstrate the unit's capability to achieve a minimum four log<sub>10</sub> reduction of *Bacillus stearothermophilus* spores.
4. The operator of the STI Chem-Clav, STI-2000CV, shall perform the following daily operational and maintenance activities and maintain permanent records of these activities and their outcome in the Facility Management Plan specified in condition 2:
- a. Each operator shall utilize a daily operating log form (Attachment A) for each unit for each day that infectious waste is treated in the unit. All daily operating logs for a treatment unit shall be grouped together and arranged by date within the grouping. The operator shall attach the strip chart recording as produced by the STI Chem-Clav treatment unit to that day's daily log. Use of the daily operational log form, Attachment A, shall satisfy the daily log requirements of Rule 3745-27-32 of the Administrative Code.

- b. Conduct annual preventative maintenance checks and services as stated in the operating manual: the STI Chem-Clav, NEW, MODERN WASTE STERILIZATION SYSTEM FOR HOSPITALS & REGIONAL FACILITIES, Operation & Maintenance Manual, revised 5/8/97.
5. The operator shall comply with all applicable rules pertaining to infectious waste treatment.
6. Wastes contaminated with non-incidentals, chemotherapeutic wastes, pathological wastes, cytotoxic agents, hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-37-51, or radioactive waste shall not be introduced into the STI Chem-Clav STI-2000CV.
7. If treatment occurs outside the parameters established in Condition 1 as a result of a malfunction of the unit due to such occurrences as jamming, overloading, electrical, or mechanical reasons, all waste contained within the treatment unit shall be managed as infectious waste. Infectious waste may be temporarily maintained within the treatment unit unless the waste becomes putrescent or becomes a food source or breeding ground for insects or rodents.
8. Sterile Technology Industries, Incorporated shall provide each purchaser with clean, copy-ready forms for both the daily log, (Attachment A) and the quality assurance testing (Attachment B) for the operator to make additional copies as necessary.
9. Sterile Technology Industries, Incorporated shall present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the STI Chem-Clav, STI-2000CV.
10. Sterile Technology Industries, Incorporated shall provide Ohio EPA with all current versions of, or any revisions to, the operating manual intended for use in Ohio. The operating manual or revisions shall not alter nor conflict with any part of this Director's approval letter, including any of the parameters specified in Condition number 1, without prior approval by the Director.
11. Sterile Technology Industries, Incorporated shall inform the Ohio EPA in writing of all new installations in the State of Ohio of the treatment unit a minimum of seven (7) days prior to installation.
12. This approval is not a substitute for a Permit-to-Install and license required by the Division of Solid and Infectious Waste Management as cited in Sections 3734.02, 3734.05, and 3734.06 of the Ohio Revised Code for off-site infectious waste treatment facilities or on-site treatment facilities that treat infectious wastes not generated on premises operated by the generator. On-site treatment facilities that treat only infectious waste generated on premises operated by the generator are not required to obtain a permit-to-install and a license under Sections 3734.02, 3734.05, and 3734.06 of the Ohio Revised Code.
13. Nothing in this approval should be interpreted to release the owner or operator of the unit from responsibility under Chapters 3704.(air pollution control statute), 3734.(solid, infectious, and hazardous waste statute), or 6111. (water pollution statute) of the Ohio Revised Code or rules promulgated thereunder. Additionally, this approval does not release the owner or operator from compliance with all other federal or local laws or regulations.
14. This STI Chem-Clav, STI-2000CV approval is not a substitute for any required Permit(s)-To-Install or Permit(s)-To-Operate to be issued for on-site or off-site treatment facilities by the Division of Air Pollution Control or the Division of Water Pollution Control.

Upon compliance with the conditions stated herein, infectious waste treated by this unit is to be: (1) handled in the same manner as solid waste, provided the material meets the definition of "solid waste" in paragraph (B) of rule 3745-27-01 of the Ohio Administrative Code for free liquids, and (2) disposed of in a licensed solid waste facility.

You are hereby notified that this action of the Director of Environmental Protection Agency (Director) is final and may be appealed to the Environmental Review Appeals Commission (ERAC) pursuant to ORC Section 3745.04. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based.

Mr. Randall McKee  
Sterile Technology Industries, Inc.  
Page 5

It must be filed with the Board within thirty (30) days after notice of the Director's action. A copy of the appeal must be served on the Director within three (3) days of filing with ERAC. An appeal may be filed with ERAC at the following address:

Environmental Review Appeals Commission  
236 East Town Street  
Columbus, Ohio 43215

Sincerely,



Donald R. Schregardus  
Director

DRS/HH/dk

attachments

cc without attachments: Jenny Tiell, Assistant Director  
Barbara Brdicka, Acting Deputy Director  
John Sadzewicz, Acting Chief, DSW

OHIO E.P.A.

SEP 16 98

ENTERED DIRECTOR'S JOURNAL



## Attachment B

### Sterile Technologies Industries, Inc.

#### STI CHEM-CLAV QUALITY ASSURANCE SPORE TEST PROCEDURE

The following procedure is required to be conducted at least once every 40 hours of operation (as per equipment hours meter on control cabinet) as a quality assurance check on the Sterile Technologies Industries, Inc., STI Chem-Clav, STI-2000CV.

Waste is not to leave the yard until the first spore test reading for that container is checked and determined to have NO GROWTH. To accomplish this we will do the following:

- Take a specific gravity test of the chemical in the storage tank.
- Check steam temperatures and pressures within normal operating parameters (Supervisor's Handbook).
- Check that the Quality Control Port (QCP) fluid flow is not blocked or restricted.
- Record all operation parameters and results onto the Quality Assurance Log (Attachment B).

\*This test should be performed during regular operation of the infectious waste treatment unit.

#### TEST PROCEDURES

STEP	PROCEDURE
1.	Obtain two (2) spore strip envelopes of <i>Bacillus stearothermophilus</i> , three (3) LB or TSA broth tubes, one (1) sealed plastic bag and one (1) "spore test carrier".
2.	Label all tubes with the current equipment hour meter reading. Place one strip envelope in the spore test carrier with 10 grams of "CLEAN" waste, then go to the STI Chem-Clav STI-2000CV.
3.	The Chem-Clav QCP assembly has two valves: "fluid entrance", and "test carrier launch" valves; and one screw plug for inserting the test carrier into the system.
4.	With the plug screwed in, open both valves in order to flush out the assembly. Have the charger read out the fluid flow, as you open the fluid flow valve. The flow should rapidly increase, if it does not, the approach lines are clogged. Go to Manual Shutdown, break the pipe union above Press on the fluid line and with fresh water from a hose, flush out the lines. Reassemble the lines, pull out Manual Stop, press reset, and check flow. Flush the assembly for one minute, then shut both valves.
5.	Crack open the launch valve. Now unscrew the plug, place the spore test carrier with the spore envelope plus 10 grams of clean waste into the test port assembly. Screw the plug back in. Crack open the fluid valve, increase total fluid flow 2GPM. Wait seven minutes. Then close the launch valve fully. Shut the fluid entrance valve. Unscrew the plug to retrieve the carrier. Screw on the plug and close the launch valve.

## STEP

## PROCEDURE

- 
6. Set the spore test carrier aside to drip for 3 minutes. After 3 minutes place the spore test carrier into the Steam Clav. Travel time through the steam section is 30 minutes. Thirty minutes after insertion, manually initiate compactor ram forward movement. When fully extended, turn the ram off. This will provide a platform for the exiting waste to fall on that you can reach. Using a rake, sift the waste for the spore test carrier. Upon location of the spore test carrier, put on a set of clean surgical rubber gloves and place the carrier into the plastic bag, reseal the bag, shut the compactor door, and turn the compactor back on (automatic cycle).
  7. Return to the "lab".
  8. Aseptically open the spore test carrier and remove the processed spore strip in its envelope.
  9. Aseptically remove the processed spore strip from its envelope, open the "TEST A" broth tube, insert processed spore strip and close.
  10. Aseptically remove the unused spore strip from its envelope, open the "CONTROL" broth tube and insert the spore strip into it. Close the "CONTROL" tube. Set it aside.
  11. Place all test tubes in holder and in incubator, at a temperature of 55-60 degrees C. The spore strips should be incubated for seven days or as specified by the manufacturer.
  12. Record all daily tube readings onto the Quality Assurance log.  
"GROWTH" = "G"; "NO GROWTH" = "NG".
  13. NG after one day, release waste container to landfill. In doubt after one day, check machine operating parameters, adjust as appropriate, hold container for three days.
    - "NG" - release to landfill
    - "G" - reprocess container
  15. "NO GROWTH" in the "CONTROL" or "GROWTH" in the BROTH ONLY Test Tubes invalidates the test. All waste in the container shall be managed as infectious waste.

