

STREET ADDRESS:

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By: Carlyle Date 12/8/95

MAILING ADDRESS:

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

December 8, 1995

RE: Approval of the STERIS EcoCycle 10™
Infectious Waste Treatment Technology

Mr. Paul Zamecnik
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

OHIO E.P.A.
DEC -8 95

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Dear Mr. Zamecnik:

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 STERIS Corporation for statewide approval was submitted on August 12, 1994. The EcoCycle 10™ operates on the principal of chemical inactivation of microorganisms with exposure for a minimum time to a minimum concentration of peracetic acid with ongoing quality assurance to ensure the successful kill of test organisms. The STERIS EcoCycle 10™ Biohazardous Waste Treatment System is a grinding/chemical disinfection unit. Chemical treatment relies on exposure of the surface area of the waste load. The unit operates for a minimum complete chemical treatment time of 10 minutes. The initial phase is a grinding process that operates for a fixed amount of time (3 minutes). During this time two opposing blades rotate at a minimum speed of 3600 rpm to increase the surface area of the waste and release the peracetic acid. The chemical soak phase of this treatment process operates for a fixed amount of time (7 minutes). The collection cap is designed to allow only a select sized waste through the opening and to prevent overflowing, as the opening extends into the canister body. Only peracetic acid is to be used to treat infectious waste in this unit. The peracetic acid is available in two different concentrations depending on the volume of blood to be treated in the waste load -- STERIS SW or STERIS LW. Waste loads containing volumes of blood less than or equal to 100 milliliters may be processed using either the STERIS SW or STERIS LW. Waste loads containing higher concentrations (greater than 100 milliliters but less than or equal to 1000 milliliters) of blood must use only STERIS LW. Waste loads containing volumes of blood greater than 1000 milliliters can not be processed using the STERIS EcoCycle 10™ Biohazardous Waste Treatment System. In addition to the appropriate concentration of peracetic acid (STERIS SW or STERIS LW), a minimum of 1.5 liters of water is to added at the beginning of each waste treatment cycle. Upon completion of the 10 minute waste treatment cycle the operator removes the processing lid of the chamber canister to examine the indicator disk before dewatering and bagging the waste for final disposal.

George V. Voinovich, Governor
Nancy P. Hollister, Lt. Governor
Donald R. Schregardus, Director

DEC 8 95

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: Kara Yule Date 12/8/95

Pursuant to the Ohio Administrative Code (OAC) Rule 3745-27-32 (A)(5) and based upon the submitted documents Application for registration, Revision 1, August 1994 and the Additional Sporicidal Efficacy Testing, Revision 2, September 1995, the STERIS EcoCycle 10™ Biohazardous Waste Treatment System is approved statewide provided each statewide installation conforms with the following conditions:

1. Each STERIS EcoCycle 10™ Biohazardous Waste Treatment System treatment unit shall be operated utilizing the following parameters:
 - a. The grinding cycle shall operate for a minimum of three minutes at the beginning of the treatment cycle. The chemical soak portion of the treatment cycle shall operate for a minimum of seven minutes.
 - b. STERIS SW, 17.1 milliliters of 35% peracetic acid or STERIS LW, 79.8 milliliters of 35% peracetic acid shall be utilized when the infectious waste load contains less than or equal to 100 milliliters of blood. STERIS LW shall be utilized when the volume of blood in the infectious waste load is greater than 100 milliliters but less than or equal to 1000 milliliters. The unit shall not treat infectious waste containing more than 1000 milliliters of blood.
 - c. The person filling the canister with infectious waste shall mark the canister with either green tape or a green label to indicate that the canister contains less than 100 milliliters of blood. The person filling the canister with infectious waste shall mark the canister with either blue tape or a blue label to indicate that the canister contains at least 100 milliliters but less than 1000 milliliters of blood. This person shall also indicate on the tape or label the estimated volume of blood in milliliters contained within the canister.
 - d. The operator shall determine which concentration of peracetic acid to use based on (b) and (c) above. The operator shall record the dosage used in each treatment cycle in a daily operating log, once the selection of the appropriate peracetic acid concentration has been made. The unit operator shall complete the entry in the daily operating log as referenced in Condition 4a.
 - e. The operator shall operate the treatment unit using only the specially designed canister that sets down inside the machine cabinetry and contains internal grinding blades.
 - f. The cap shall be kept on the canister when the canister is in use as an infectious waste receptacle. The cap shall not be removed prior to arrival at the processing area. The collection cap is to be removed before processing.
 - g. The collection cap shall be disinfected after each use with a U.S. EPA registered disinfectant that is also tuberculocidal.
 - h. The operator shall examine the indicator disk upon completion of the treatment cycle and before the waste is dewatered and bagged. The entire indicator on the disk must have a visible color change as an indication that STERIS was used during the process. If

there is not a complete color change, then the waste is not considered treated and shall be treated again with either a new charge of the appropriate STERIS concentration and a new indicator disk or an approved treatment method in accordance with OAC Rule 3745-27-32.

2. The operator shall develop and maintain in one area on the premises of the infectious waste treatment unit a Facility Management Plan (FMP) pursuant to Paragraph (E)(1) of OAC Rule 3745-27-32, excluding Paragraph (E)(1)(a)(xii). 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 STERIS EcoCycle 10™.
 - b. A statement signed by each person filling the canister with infectious waste certifying that the operator of the treatment unit has provided instruction on the use of the canister, the types of infectious waste the unit is approved to treat, the designation of the volume of blood contained within a canister to be treated, and the appropriate color marking of the canister with a label or tape as specified in condition 1.
 - c. 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 log₁₀ reduction of *Bacillus subtilis* spores.
4. The operator of the STERIS EcoCycle 10™ Biohazardous Waste Treatment System, 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. Use of the daily operational log form, Attachment A, shall satisfy the requirements of Paragraph (E)(3) of OAC Rule 3745-27-32.
 - b. Conduct annual preventative maintenance checks and services as stated in the operating manual.
5. The operator shall comply with all applicable rules pertaining to infectious waste treatment. At the date of this approval, the applicable Paragraphs are Paragraphs (E), (K)(1), (M), (N), (O), (P), (R), and (S) of OAC Rule 3745-27-32 except Paragraphs (E)(7) and (E)(8).

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6. Wastes contaminated with non-incidentally quantities of chemicals, body parts containing bone, organs, whole carcasses, 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 STERIS EcoCycle 10™ Biohazardous Waste Treatment System.
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 unit shall be managed as infectious waste and the canister disinfected with a U.S. EPA registered disinfectant that is also tuberculocidal. Infectious waste may be temporarily maintained within the unit unless the waste becomes putrescent or becomes a food source or breeding ground for insects or rodents.
8. STERIS Corporation shall provide each purchaser with a clean, copy-ready daily log form, (Attachment A) for the operator to make additional copies as necessary.
9. STERIS Corporation must present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the STERIS EcoCycle 10™ Biohazardous Waste Treatment System.
10. STERIS Corporation shall provide Ohio EPA with any updates to the operating manuals that significantly impact the use or operation of the system within 30 days of the manual change.
11. STERIS Corporation shall provide Ohio EPA with a list of new installations of the treatment unit on a quarterly basis.
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 STERIS EcoCycle 10™ Biohazard Waste Treatment System 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 (III) of rule 3745-27-01 of the Ohio Administrative Code for free liquids, and (2) disposed of in a licensed solid waste facility.

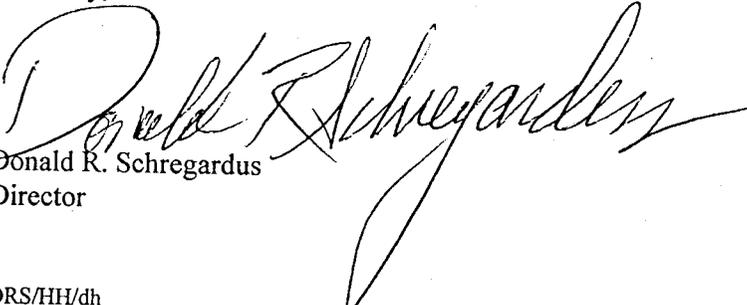
I certify this to be a true and accurate copy of the official document as filed in the records of the Ohio Environmental Protection Agency.

By: Kara Yelen Date 12/8/95

You are hereby notified that this action of the Director of Environmental Protection Agency (Director) is final and may be appealed to the Environmental Board of Review (Board) 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. 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 the Board. An appeal may be filed with the Board at the following address:

Environmental Board of Review
236 East Town Street
Columbus, Ohio 43215

Sincerely,



Donald R. Schregardus
Director

DRS/HH/dh

Attachment

cc: Jenny Tiell, Deputy Director
Barbara Brdicka, Chief, DSIWM
Tom Behlen, Chief, DSW

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By: Karapala Date 12/8/95

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