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State of Ohio Environmental Protection Agency

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George V. Voinovich
Governor

Donald R. Schregardus
Director

August 9, 1993

Suzanne E. Helton
ABB Sanitec, Inc.
Wayne Interchange Plaza II
155 Route 146 West
Wayne, New Jersey 07470

Re: OAC 3745-27-32 (A)(4)
Approval of the ABB Microwave Disinfection System, Models HG-A 250 S and HG-A 100 S

Dear Ms. Helton:

The Ohio EPA expends considerable effort to be responsive to the needs of hospitals and universities 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 expanded the current alternative infectious waste treatment approval process to include the option of approving a model of equipment at a specific location provided Ohio EPA's validation standard is met. As you are aware, Ohio EPA's current approval process allows for the approval of an alternative infectious waste treatment technology statewide based on the submission of data, prior to approval, that demonstrates the successful completion of efficacy testing as outlined below.

Based on the new approval option and a request by ABB Sanitec, Inc. dated July 26, 1993, I am issuing the following site specific approval with a validation testing requirement by each operator for the use of the ABB Microwave Disinfection System, Models HG-A 250 S and HG-A 100 S, in Ohio.

The microwave unit operates on the principal of thermal inactivation of microorganisms with exposure for a minimum time at a minimum temperature with initial and ongoing quality control testing to ensure the successful kill of test organisms. Waste is heated to a minimum temperature (95°C) and maintained at that temperature for a minimum period of time (at least 30 minutes). Within the microwave unit, the attainment of the temperature is accomplished by initially heating the shredded waste with steam and then further enhancing the temperature by non-ionizing radiation utilizing a series of six microwave generators in the Model HG-A 250 S and four microwave generators in the Model HG-A 100 S. The exposure time of the waste to the specified minimum temperature is controlled by the speed of the auger screw. This process is automatic but not necessarily continuous. An auger screw moves the waste through the microwave section into a holding section in the case of the 250 S unit and from the microwave section in the case of the 100 S unit to an optional second grinder or particalizer. The holding section screw speed is fixed (7.2 rpm) for the HG-A 250 S model. There is no holding section or holding section screw in the HG-A 100 S unit. The microwave screw has a maximum speed so that the infectious waste will not move through the unit faster than treatment can be attained. The speed of the microwave screw will vary up to the maximum speed due to variations in temperature and to different densities of the waste charged into the unit (0 rpm, 0.5 rpm, 1.0 rpm, 0.75 rpm under manual). The speed of the auger screw in the microwave section is self-adjusting depending upon the temperature of the microwave section. The screw will slow when the temperature falls below a certain point due to waste density or other reasons. Therefore, the total time to treat any particular load of infectious waste will vary above the 30 minute minimum based upon the unit's capability to heat the waste charged to the 95°C minimum temperature and to demonstrate successful kill of test organisms.

Pursuant to the Ohio Administrative Code (OAC) 3745-27-32 (A)(4) and based upon the submitted documents Technical Manual, Operation and Maintenance for Microwave Disinfection Unit, Model HG-A 250 S, Revision 1, January 1993 and Sanitec Microwave Disinfection System for Regulated Medical Waste, Confidential Technology Disclosure, Revision 4, April 24, 1991, and acknowledgment by ABB Sanitec officials that the HG-A 100 S model works exactly like the HG-A 250 S model, the ABB Microwave Disinfection System, Models HG-A 250 S and HG-A 100 S, are approved provided each site specific installation conforms with the following:

1. Each site specific installation of the Model HG-A 250 S or Model HG-A 100 S is operated utilizing the following parameters:

   Screw speed of the microwave treatment section shall be a maximum of 1.0 rpm and the screw speed of the temperature holding section (for the HG-A 250 S only) shall be a maximum of 7.2 rpm both during the validation testing as specified in Condition 2. below and during normal operations. The maximum pore size of the high efficiency particulate air (HEPA) filter shall be 0.12 microns, as specified in the submitted documents cited above. The minimum processing temperature shall be 95^{0}C for each site specific unit throughout validation testing and during normal operations. The minimum processing time shall be 30 minutes throughout validation testing and during normal operations. For purposes of the approval, the processing time is defined as the time measured by tracking a sample commencing upon introduction of the sample after the shredder and ending with immediate retrieval prior to the temperature holding section but after discharge from the microwave treatment section for the 250 S unit and prior to the particalizer and after discharge from the microwave section in the 100 S unit.

2. Prior to full operation of the unit, the operator of each model must perform validation testing by demonstrating the unit's capability to achieve the following performance standard: a minimum four $\log_{10}$ reduction of *Bacillus subtilis* spores, for every spore strip retrieved intact, by the use of spore strips within glassine envelopes. Validation testing shall be conducted in accordance with the following:

   a. Infectious waste must be used during validation testing. The waste must either be held until results are obtained which demonstrate the achievement of the validation standard stated above, indicating successful treatment, or must be treated using another approved infectious waste treatment method. Infectious waste used for the validation testing must be representative of the site's waste stream. Representative means that the total amount of waste charged shall be comprised of infectious waste from all units, wards, floors, or customers of the facility that will normally produce infectious waste for treatment by the microwave unit. The microwave unit shall be operated so that at no time during the testing shall the microwave section screw stop due to lack of sufficient waste to the hopper and shredder. The cart that feeds the unit shall be kept full and then when the unit calls for a charge the operator shall immediately charge the unit with another waste load.

b. The spore strip validation testing shall be conducted in accordance with "Attachment A: Validation Testing Protocol" with four test runs. The test runs are to be conducted to demonstrate processing of the representative waste streams that the operator would handle during normal operation. At a minimum, two test runs must be done at start-up when infectious waste first enters the microwave section and the auger screw has begun to turn. The remaining two test runs shall be conducted after several carts of infectious waste have been charged into the machine.

c. All results from the validation testing shall be submitted to the Infectious Waste Unit, Division of Solid and Infectious Waste Management, Ohio EPA - Central Office, for review.

d. All operational parameters established for the unit in Condition 1. must be utilized throughout the validation testing.

e. The protocol used and results obtained during the validation testing must be maintained on-site by the operator for the life of the unit.

f. Before initiating the site specific validation testing, the operator must notify the Ohio EPA, Division of Solid and Infectious Waste Management, Infectious Waste Unit at least 14 days in advance. Representatives from the Ohio EPA or approved health department may witness the validation testing.

3. If validation testing proves that the unit is capable of meeting the performance standard outlined in Condition 2., the unit can be used for the treatment of infectious waste. If the validation testing does not prove that the unit is capable of achieving the performance standard, then the operator must cease infectious waste treatment immediately. All waste in the unit must be removed and treated as infectious waste and any waste that has been through the unit but which remained on-site must be treated as infectious waste. The entire validation procedure, outlined in Condition 2., must be repeated with successful attainment of the performance standard before the unit can be used to treat infectious waste.

4. Operators of the ABB Microwave Disinfection System, Model HG-A 250 S or HG-A 100 S, shall perform the following activities both during validation testing and normal operations and maintain permanent records of the activities and the results of the activities for a period of three years:

a. Calibrating all temperature sensors a minimum of annually.

b. Maintaining all automated permanent chart recordings of the microwave section entry temperature, the temperature holding section temperature, and the microwave section screw speed.

c. Recording the operator's name(s), the time that the first and last charges of waste entered the unit each day, and the weight of each charge into the unit each day in a daily operating log.

d. Calibrating, maintaining, and repairing the unit and daily, weekly, monthly, and annual preventative maintenance checks and services as stated in the operating manual.

e. Quality control testing as outlined in Condition 5. below.

5. Every week, after successful validation testing results are obtained, the operator of the ABB Microwave Disinfection System, Model HG-A 250 S or HG-A 100 S , shall conduct the following quality control tests under full load conditions to assure that the validation standard is consistently achieved:

a. The spore testing must be conducted in accordance with the protocol described in Condition 2.a. and 2.b. above, except that the number of spore strips may be decreased from 50 strips to 10 strips and each quality control test shall consist of a single test run. A maximum of one spore strip may be positive for growth of *Bacillus subtilis* to achieve the quality control standard. In addition, spore testing shall commence at the time when waste first enters the microwave section and the auger screw has begun to turn.

b. If more than one of the spore strips are positive for growth at anytime during the seven day incubation period or if the minimum treatment time and/or minimum treatment temperature outlined in Condition 1. is not met, Condition 5.a. must be repeated immediately. If, upon obtaining the results of the repeated test, more than one of the spore strips are positive for growth, then infectious wastes may not be treated in the unit and must be diverted and treated by another approved infectious waste treatment method. Wastes which have been through the unit prior to or during the failed quality control test that still remain on-site must be handled as infectious waste. The source of the problem must be determined and another validation test, as described in Condition 2., must be successfully completed prior to the unit being used to treat infectious wastes.

6. Wastes contaminated with cytotoxic agents, hazardous waste as defined in 40 CFR Part 261 and OAC Chapter 3745-37-51, and radioactive waste shall not be introduced into the Model HG-A 250 S or HG-A 100 S unit.

7. Human and animal pathological wastes, except body parts, organs, and carcasses, may be introduced into the unit.

8. 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. Infectious waste may be maintained within the unit unless the waste becomes putrescent or becomes a food source or breeding ground for insects or rodents.

9. ABB must present a copy of this letter, prior to purchase, to each prospective purchaser or operator of the Model HG-A 250 S or HG-A 100 S unit.

10. ABB shall provide Ohio EPA with updated inserts to the manuals referenced in the beginning of the correspondence within 30 days of the manual change.

11. A facility that treats infectious waste by the ABB Microwave Disinfection System, Model HG-A 250 S or HG-A 100 S, is defined as an infectious waste treatment facility and is required to comply with all applicable sections of Rule 3745-27-32 of the Ohio Administrative Code.

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.

Note: This ABB Microwave Disinfection 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.

Should ABB wish to obtain statewide approval of microwave treatment technology, as described in paragraph one above, ABB must submit a separate request to the Director of the Ohio EPA. This request is to be based on the Division of Solid and Infectious Waste Management's efficacy standard of the attainment of a five $\log_{10}$ reduction in *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Mycobacterium bovis*, *Aspergillus niger*, *Giardia* species cysts, and Poliovirus; and a four $\log_{10}$ reduction in *Bacillus subtilis* spores. ABB must submit the testing protocol and receive written concurrence by the Division of Solid and Infectious Waste Management prior to the commencement of efficacy testing. The protocol must include experimental controls and the actual processing of waste through the HG-A 250 S or HG-A 100 S unit. Waste processed through the unit must be inoculated with a minimum microbial challenge population of 10^6 organisms per gram of waste such that the reduction in the challenge population can be calculated. Microorganisms, parasites, viruses, or spores may not be placed into sealed vessels during testing. The protocol must conform with the general protocol guidance issued by the Division of Solid and Infectious Waste Management and must utilize verified scientific microbial technique. Infectious waste shall be used

during efficacy testing. The untreated infectious waste used during the testing, must either be held until concurrence is obtained from the Division of Solid and Infectious Waste Management that the data demonstrate the attainment of a five $\log_{10}$ reduction in *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Mycobacterium bovis*, *Aspergillus niger*, *Giardia* species cysts, and Poliovirus; and a four $\log_{10}$ reduction in *Bacillus subtilis* spores; or must be treated using an approved infectious waste treatment method. Prior to any permanent changes to the operational parameters specified in the statewide approval application once it is approved by Ohio EPA, ABB must submit data and provide all calculations to demonstrate that the efficacy standard was obtained; and receive written concurrence from the Division of Solid and Infectious Waste Management for the permanent change of operational parameters.

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 ground 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/clk

attachment

cc: Jim Burns, Governor's Office
Jenny Tiell, Acting Deputy Director
Barbara Brdicka, Chief, DSIWM
Alison Shockley, DSIWM
Bob Rothwell, Chief, DWPC
Bob Hodanbosi, Chief, DAPC

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: Mary Cavin Date 8-9-93

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RECORD DIRECTOR'S JOURNAL

ATTACHMENT A

TESTING PROTOCOL

This testing protocol shall be followed for both the validation testing and the weekly quality control testing, except that the quality control testing requires processing only ten test spore strips and two control spore strips per test. The microwave disinfection system shall be operated in automatic mode.

1. OBJECTIVE:

The objective of the validation testing is to confirm the efficacy of the ABB Sanitec Microwave Disinfection System, Model HG-A 250 S or Model HG-A 100 S by demonstrating a 4 $\log_{10}$ reduction in the challenge population of *Bacillus subtilis* spores.

2. TEST INDICATOR:

A. The test indicator microorganism shall be only the *Bacillus subtilis* spore on a strip which is contained in a glassine envelope.

B. Spore strips shall contain 10^4 or 10^6 spores. If spore strips containing 10^6 spores are chosen for the testing, a 6 $\log_{10}$ reduction shall occur as demonstrated by the inactivation of the spores. Commercially available spores strips of sufficient population and description are acceptable.

C. Each glassine envelope shall be placed into a brightly colored cloth sock for easy retrieval and numbered with a waterproof marker.

D. No test spore strip or microorganism shall be in a sealed vessel during testing.

3. TEST PROCEDURE:

A. Each test run shall consist of 50 test spore strip samples and 4 control spore strip samples.

1. Test spores are to be introduced into the system every minute. The sample containing socks are to be inserted into the sample port at the transfer hopper beneath the shredder; this point is after the shredder and before the steam injection and microwave generators.

2. The four control samples are to be placed into cloth socks and handled (received, transported, etc.) in the same exact manner as the test samples except they shall not be processed through the system. These control samples serve to ensure that the test samples are not inadvertently inactivated by some other step in the protocol.

B. The following parameters shall be recorded:

1. Date of testing; and

2. Name of the responsible test manager; and

3. Sources of the representative test load, as defined in Condition 2.a. of the approval, (ie. laboratory, patient floor, surgery, etc.); and

4. Source, name, and lot number of the biological indicator; and

5. Time the system start-up cycle was initiated; and

6. Time of each sample's insertion into the unit; and

7. Time of each sample's discharge from the unit prior to the particalizer; and

8. Calculate and record the treatment time of each sample, i.e. subtract time-in from time-out; and

9. As each test sample is inserted into the unit record:

   a. Temperature of the microwave section at the entry (between microwave generators 1 and 2) and exit (between microwave generators 5 and 6) locations; and

   b. Exit temperature of the temperature holding section; and

   c. Steam temperature; and

10. Results of spore germination; and

11. Any comments, observations, or irregularities or upset conditions.

C. The permanently recorded strip chart produced by the chart recorder shall be submitted as part of the validation procedure.

D. Immediately upon retrieval of a spore strip containing sack from the temperature holding section procedure D.1. or D.2. shall be utilized to inoculate the cultures:

1.a. Aseptically open the exposed glassine envelopes. Carefully withdraw the spore strip from the envelope with sterile forceps and immerse each strip into a separate culture tube containing 10 ml of sterile soybean casein digest medium. Flame forceps prior to the transfer of another strip. Repeat this procedure for each spore strip. Note: The spore strips may not be collected over the duration of the validation testing and then transferred to another location for inoculation into media.

b. Aseptically open the unexposed glassine envelopes (controls). Carefully withdraw the spore strip from the envelope with sterile forceps and immerse each one in a culture tube containing 10 ml of sterile soybean casein digest medium. Flame forceps prior to the transfer of another strip. Repeat this procedure for each test and control spore strip.

c. Incubate all the tubes for 7 days at 37°C. Observe the tubes daily during the incubation period. If turbidity develops in the medium of the treated spore strips at any time during the incubation period, it is indicative of bacterial growth ... presumably due to the spores having survived the disinfection process. Gram stains and additional identification

procedures, such as morphologic and metabolic characterizations, must be performed on all tubes that are turbid to verify that the microorganisms present are not *Bacillus subtilis*.

2. If immediate inoculation is not possible, then the spore strips shall be removed from the socks and immediately cooled to prevent further destruction of the spores. Inoculation shall then be accomplished after retrieval of all socks containing spore strips and shall follow the procedure outlined in paragraph D.1. of the test procedure.