From:	Joe Delloiacovo
To:	Wren, Kira
Cc:	Hummel, Lindsey; Sol Fried; Jay Liberman; Kreke, Thomas; Markert, Elizabeth; RAMAN, SHYAMALA; HARPER, DANIEL
Subject:	Re: Cyntox LLC Permit Transfer and Renewal Approvals -- C13 Condition Revision
Date:	Tuesday, April 16, 2024 2:37:15 PM
Attachments:	image001.png image002.png image003.png image004.png image005.png image006.png image007.png image008.png image009.png image010.png image011.png image012.png image013.png image014.png Confidential Information Section - MedAssure SWPF Permit App.pdf

Kira,

Thanks for your quick reply on our message about a permit condition revision.

The MDU is designed to thermally treat infectious waste using a combination of moist heat and microwave energy. The microbiological efficacy standard for treatment is a log 6 reduction of bacteria spores achieved by exposure to a minimum temperature and time. In the case of the MDU, these processing parameters are a minimum of 95 ^{0}C for a minimum of 30 minutes. Various microbiological efficacy studies on the MDU have demonstrated this performance, including the testing reports provided to IDEM over the years. The MDU processing computer control system is designed to ensure that these conditions are maintained or the MDU will automatically stop operation.

The design of the MDU has not changed since the original submittal permit to IDEM in 2011. Attachment 1 of the original 2011 submittal is included for convenience. I believe that the discussions on how the MDU is designed to function in recent times have mixed general informational statements with actual equipment design features, which has caused some misunderstandings.

Starting on page 10 of Attachment 1, you will find the "MDU System Description and Process Control" chapter of the operating manual. Section 2-10 TEMPERATURE CONTROL & FAULTS STATES:

> "Microwave radiation is introduced along the length of the microwave segment by six (6)
> microwave generators (MWG). A temperature sensor located between MWG #2 and MWG #3

monitors the MWS Entry Temperature. If low temperature exists for too long a period of time, the
MWS Entry Temperature will go to fault. A temperature sensor located between MWG #5 and
MWG #6, monitors the temperature of the material as it exits the MWS (MWS Exit Temperature).
During system operation the MWS screw speed is determined by the MWS Exit Temperature.

If the material temperature is below 203 ^{0}F (95 ^{0}C), the MWS screw will run at 50% full speed.
If the material temperature is 203 ^{0}F (95 $_0$C) or above, the MWS screw will run at 100% (Full
Speed). The MWS Exit Temperature is enabled when MWG #5 is enabled. The MWS Exit
Temperature will go to fault after 5 minutes of low temperature only when enabled."

Temperature for treatment assurance is the operating condition in the MWS Screw, not the steam generator. The MWS screw operates at atmospheric pressure. As saturated steam is injected, regardless of steam generator pressure, it will immediately condense into saturated liquid and, at atmospheric conditions, the temperature will equalize at roughly 212 ^{0}F (100 ^{0}C).

The relationship of the Steam Generator and its importance to the MDU performance relates to adequate steam supply. As steam is drawn from the Steam Generator, the steam drum pressure will drop as will the steam temperature. The MDU computer process control system monitors the steam temperature in the steam generator.

The MDU control system setpoint for steam temperature in the Steam Generator is 162 ^{0}C (80 PSIG). The MDU computer logic will allow the MDU to operate as long as the temperature is above 150 ^{0}C (50 PSIG). If steam flow is drawn at a rate higher than the Steam Generator can produce, the steam temperature will drop as pressure cannot be maintained. The MDU is programmed to stop operation if this occurs, which assumes that the Steam Generator is not functioning properly and needs to be addressed. Section 2-17 STEAM GENERATOR states:

"The PLC monitors the steam generator and determines its operating status. Upon automatic
start-up, the steam generator begins to warm up. When the steam temperature reaches 150 ^{0}C
the PLC starts the system. If this temperature is not reached within several minutes, the system
will go to fault. If the steam temperature drops below 150 ^{0}C and does not

recover after a period of
time, the system goes into "sleep mode". In the "sleep mode" the system is automatically
stopped to allow the steam generator time to recover (steam generator remains ON). When the
system is in sleep mode, the PLC waits for the steam temperature to reach 150 ^{0}C before
returning the system to automatic operation. This assures that the steam generator has built up
a sufficient supply of steam. If this temperature is not reached after several minutes, the system
will go to fault."

The Steam Generator's rated capacity for steam flow is more than the MDU needs for normal operation. So, the continuing drop in steam temperature (lower pressure), means the steam generator is at fault and needs attention.

Currently, the language under C13 (d) pertains to the differential pressure switch designed into the Steam Generator for the purposes of the energizing the electric elements in the steam drum to boil off steam. At 72 PSIG, the switch energizes the heating elements and at 80 PSIG (the normal operating pressure), the switch cuts power to the heating elements. The steam generation is an on/off function, not continuous. If steam is drawn off at a rate more than the Steam Generator can produce, the pressure will continue to drop until the water level diminishes to a point where level sensors in the steam drum shutdown the Steam Generator to prevent burnout for the heating elements and other component damage. The only process sensor integration with the MDU control system is steam temperature. There is no link between the MDU controls and the Steam Generator differential switch. So, it is inaccurate to assume the operator can control or meet with condition as currently written. Nor is it necessary to ensure that the waste is treated to the required microbiological efficacy.

So, we recommend that the language under C13 (d) be revised to reflect the actual design of the system as follows:

C13 (d~~) The differential setting pressure should allow the pressure to drop no more than 8 PSIG below the control setpoint of 80 PSIG~~. **The MDU shall not operate if the steam temperature reaches below 150 ^{0}C.**

If needed, we can have a conference call to address any remaining questions. Thanks.

Best Regards!

Joe Delloiacovo

Executive VP – Customer Support & Technology

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C (201) 230-2913

E joed@cyntox.com

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****

FOR SERVICE CALL OR EMAIL DISPATCH at 855-429-6869, ext. 194 or Dispatch@cyntox.com

****

From: "Wren, Kira" <KWren@idem.IN.gov>
Date: Tuesday, April 16, 2024 at 9:31 AM
To: Joe Delloiacovo <joed@cyntox.com>
Cc: "Hummel, Lindsey" <LHummel@idem.IN.gov>, Sol Fried <sfried@cyntox.com>, Jay Liberman <jl@cyntox.com>, Thomas Kreke <TKreke@idem.IN.gov>, "Markert, Elizabeth" <EMarkert@idem.IN.gov>, "RAMAN, SHYAMALA" <SRAMAN@idem.IN.gov>, Daniel Harper <DHARPER@idem.IN.gov>
Subject: RE: Cyntox LLC Permit Transfer and Renewal Approvals -- C13 Condition Revision

Joe,

Please move forward with the submittal to request this revision. This request does not require a minor modification.

Thank you,

Kira Wren
Environmental Manager | Solid Waste Permits Section |
Permits Branch | Office of Land Quality
Indiana Department of Environmental Management
KWren@IDEM.IN.gov (317) 233-7090

☐ | ☐ | ☐ | ☐ | ☐ | www.idem.**IN**.gov

From: Joe Delloiacovo <joed@cyntox.com>
Sent: Tuesday, April 16, 2024 8:30 AM
To: Wren, Kira <KWren@idem.IN.gov>
Cc: Hummel, Lindsey <LHummel@idem.IN.gov>; Sol Fried <sfried@cyntox.com>; Jay Liberman <jl@cyntox.com>
Subject: Re: Cyntox LLC Permit Transfer and Renewal Approvals -- C13 Condition Revision

Importance: High

**** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ****

Good morning Kira,

As you may know, the Cyntox permit was renewed recognizing that Condition C13 was under discussion for a revision to accurately reflect the MDU design parameters.

We would like to move forward with a submittal to request this revision. Should we submit a minor permit modification or file an Appeal through the Office of Environmental Adjudication?

Please let us know as soon as possible. Thanks.

Best Regards!

Joe Delloiacovo
Executive VP – Customer Support & Technology

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****

FOR SERVICE CALL OR EMAIL DISPATCH at 855-429-6869, ext. 194 or Dispatch@cyntox.com

****

From: Joe Delloiacovo <joed@cyntox.com>
Date: Thursday, April 11, 2024 at 1:45 PM
To: "Hummel, Lindsey" <LHummel@idem.IN.gov>
Cc: "Wren, Kira" <KWren@idem.IN.gov>
Subject: Re: Cyntox LLC Permit Transfer and Renewal Approvals

Hi Lindsey,

Thanks for the introduction and it has been a pleasure working with you over the years. I look forward to working with Kira in future.

If helpful, I would be willing to have a call with Kira after she gets up to speed

to address any questions. Cyntox will be submitting a request for changed language for C13 once we get the new permit. As we have explained, the current language does not accurately reflect how the NDU is designed to function. Thanks.

Best Regards!

Joe Delloiacovo
Executive VP – Customer Support & Technology

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****

FOR SERVICE CALL OR EMAIL DISPATCH at 855-429-6869, ext. 194 or Dispatch@cyntox.com

****

From: "Hummel, Lindsey" <LHummel@idem.IN.gov>
Date: Thursday, April 11, 2024 at 10:42 AM
To: Joe Delloiacovo <joed@cyntox.com>
Cc: "Wren, Kira" <KWren@idem.IN.gov>
Subject: FW: Cyntox LLC Permit Transfer and Renewal Approvals

Good Morning, Joe,

I wanted to let you know that there will be a new solid waste permit manager for the Cyntox facility, Kira Wren. This would have been transitioned earlier but for the extended timeline for the permit transfer and renewal applications.

I will be assisting Kira with getting up to speed on this facility, as well as with the coordination of changing the C13 requirement language if you choose to submit the change request.

Thank you,
Lindsey

Indiana Department of Environmental Management
Lindsey Hummel (she/her)
Senior Environmental Manager
Solid Waste Permits Section
Permits Branch | Office of Land Quality

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Protecting Hoosiers and Our Environment
www.idem.IN.gov

From: Poe, Diane L <dpoe@idem.IN.gov>
Sent: Thursday, April 11, 2024 10:30 AM
To: joed@cyntox.com; sp@opalhs.com
Cc: S35@iga.in.gov; H91@iga.in.gov; wqhmm@marionhealth.org; barbara.lawrence@indy.gov; 'joseph.oconnor@indy.gov' <joseph.oconnor@indy.gov>; myla.eldridge@indy.gov; 'kasey.kendrick@indy.gov' <kasey.kendrick@indy.gov>
Subject: Cyntox LLC Permit Transfer and Renewal Approvals

Attached is correspondence regarding the above property in Marion County. A hardcopy will **not** be sent to the addressees.

If you have any questions, please contact Kira Wren, permit manager. Her information is in the last paragraph of page 2 above Mr. Kreke's signature block.

Note: With the issuance of these approvals, Kira Wren will be taking over permit management of this site from Lindsey Hummel, whose contact information is on the library letter (page 20). Either will be able to assist you.

Indiana Department of
Environmental Management
Diane Poe
OLQ Permits Branch Administrative Assistant
• (317) 232-4473 • dpoe@idem.IN.gov

Protecting Hoosiers and Our Environment
www.idem.IN.gov

CONFIDENTIAL INFORMATION

- MDU Technical & Performance Specification - ATT I
- NYS Sanitec MDU - Efficacy Study - ATT II.
- Illinois - Sanitec Efficacy Studies ATT III
- Performance Specification & Efficacy Testing - ATT IV
- Sanitec - Sample Approval Letters ATT V.
- SAFETY SUMMARY - ATT VI.

(*Confidential Information submitted in separate envelopes)*

MedAssure of Indiana Treatment Facility
1013 S. Girls School Road
Indianapolis, IN 46231

MEDICAL WASTE MICROWAVE DISINFECTION UNIT

TECHNICAL SPECIFICATION & ENVIRONMENTAL PERFORMANCE

Table of Contents

GENERAL INFORMATION 1

1 - 1. INTRODUCTION

This document contains technical information for the Microwave Disinfection Unit (MDU) Model HG-A-250S. The MDU is a product of SANITEC of Sun Valley, California.

The document is written to provide the necessary functional explanation of components and the overall system so one can fully understand how the SANITEC MDU processing medical infectious waste with absolute certainty.

The Sanitec Microwave Disinfection Unit (MDU) is designed to shred and disinfect biomedical waste. When operated in accordance with all of Sanitec's written procedures and instructions, properly operated systems will render biomedical waste disinfected, unrecognizable, and of no greater risk to the public health than (normally associated with) residential household waste.

The disinfection process is computer controlled with an Allen-Bradley Touch Screen system. Under normal operating conditions (automatic mode), operators need only charge the system with biomedical waste. The Unit has a hydraulic lift mechanism to hoist waste containers and drop waste into a hopper on top of the unit. The hopper has a sealed lid that opens and closes automatically. Inside the hopper, the bags and boxes of waste are directed towards a shredding device by a feed arm. The feed arm assists in forcing material into the shredder. Sensors monitor the amount of material moving into the hopper. Shredded material falls onto an auger-driven conveyor. As the waste enters the auger-driven conveyor, 162 ^{0}C (324 ^{0}F) steam is injected and conveyed through the microwave conveyor section. A series of microwave generators input energy to maintain uniform heating of the waste at a minimum temperature of 95 ^{0}C (203 ^{0}F). The waste is then transported to a Temperature Holding Section.] The final temperature and time profile is a minimum of 95 ^{0}C (203 ^{0}F) for 30 minutes. The final waste product then falls into a dumpster or similar waste transport container that may be used to transport the disinfected waste to a repository. Figure 1-1 shows a graphic illustration of the MDU and its subsystems.

The SANITEC MDU exceeds the efficacy performance requirements of the State and Territorial Association on Alternative Treatment Technologies (STAATT) achieving greater than log 4 reduction of bacterial spores. The SANITEC MDU has been approved or accepted throughout the US and in many countries around the world.

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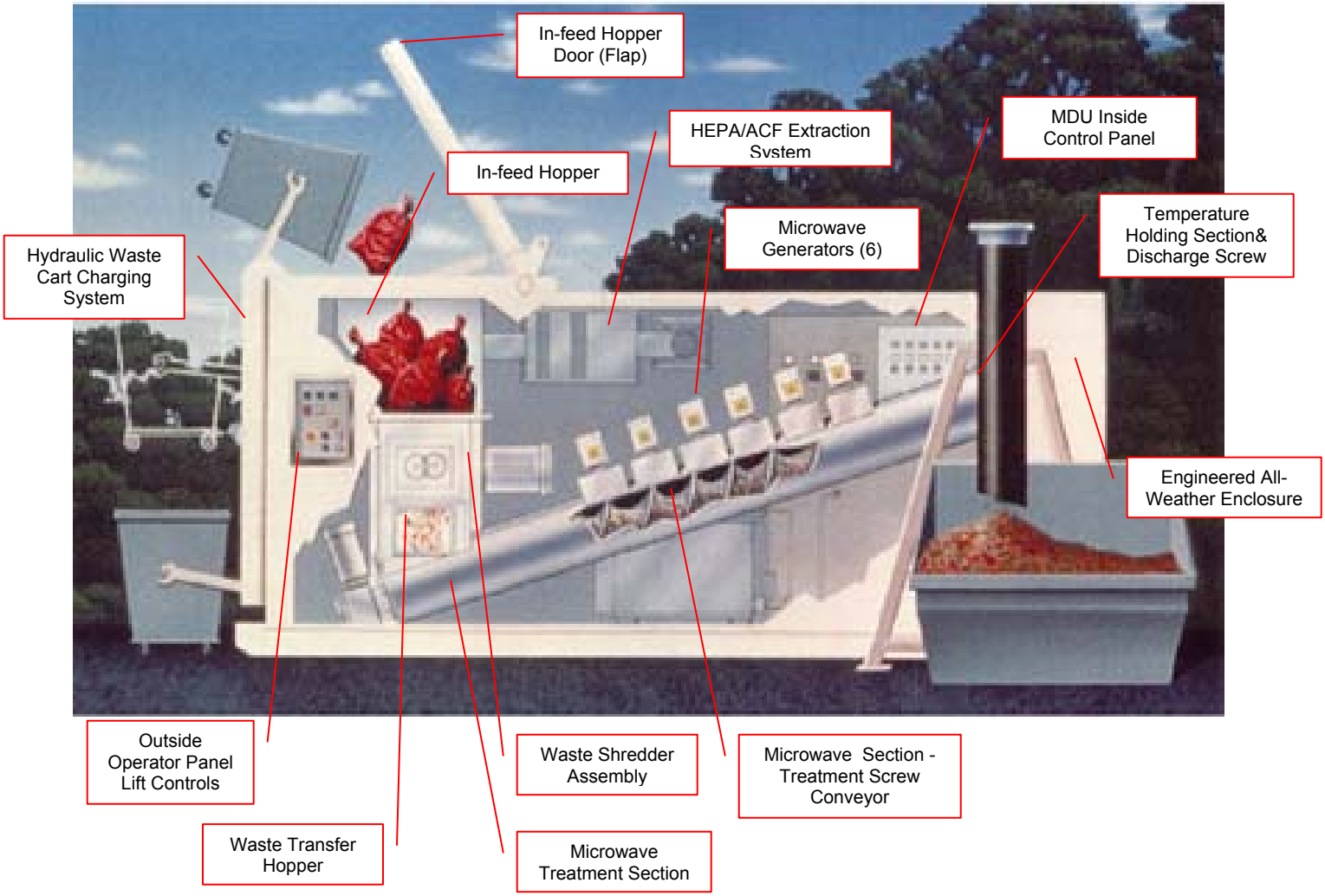
1-2. TECHNICAL DATA

The overall pertinent technical characteristics of the MDU are listed in Table 1-1. The identification and technical characteristics of units/systems associated with the MDU are listed in Table 1-2.

GENERAL INFORMATION 1

Figure 1-1 Microwave Disinfection Unit (MDU) Graphic Illustration



GENERAL INFORMATION 1

TABLE 1 - 1 - MDU GENERAL TECHNICAL CHARACTERISTICS

PARAMETER	*SPECIFICATIONS*	
Overall Dimensions		
Length Width Height Height With Flap Open Weight	24'- 6" (7,467 mm) 9' - 4" (2,845 mm) 10'-11" (3,327 mm) 17'(5,181 mm) 22,000 lbs (10,000 kg)	
Waste Throughput Capacity Based on an average waste density of 11 lb/ft ^{3} (180 kg/m^3)	Up to 1800 lb/hr (818 kg/hr)	
Water Connection	3/4 inch N.P.T. (10 gal/hr or 38 liters/hr)	
In-feed Hopper, Microwave Screw, and Discharge Screw Material Composition	Stainless steel product housing and waste contact surfaces with external insulation / with cover	
Electrical Power Requirements Input Voltage Amperage Frequency Phase Power Consumption (Nominal)	460/480 VAC 150Amps 3 phase (with ground) 60 Hz 75 kW	400/380 VAC 150 Amps 3 phase (with ground) 50 Hz 75 kW

GENERAL INFORMATION 1

TABLE 1 - 2 ♦ MDU DETAIL TECHNICAL SPECIFICATIONS - COMPONENTS

SYSTEM / UNIT	*SPECIFICATIONS*	
Waste Cart Charging System	Hopper Door	58.75 in. (149 cm) wide x 68 in. (173 cm) long
	Hydraulic Cylinder	3" bore 16" stroke, 3 / - SAE pots, 2500 psig (17.23 MPa) maximum operating pressure
	Charging Frame	Fabricated from 2x4, 2x3 x 3/16 Tube and 1 / 2 in. thick HRMS
In-feed Hopper	Size	1.5 cubic yards (1.15 cubic meters) usable capacity
	Feed Arm	1 / 2 HP 460/400 VAC/60/50 Hz/3phase with brake, 3 lb (6.6 kg)
	Air Extraction Duct	8 inch (20.32 cm) diameter
	Steam Connection	four - 3/8" NPT ports
	Water Connection	four - 3/8" NPT ports
	Insulation	2 in. thick
***Extraction Filter* System**	Air Capacity	550 CFM (15.6 m^3/min.) @ 1.4 in. WG (0.4 Kpa)
	Differential Pressure Gauge	0 -1.5 Kpa (0.21 psig)
	Blower Fan Motor	2 HP, 460/400 VAC/60/50 Hz/3 phase
	Pre-filter Cartridge	4 pocket Viscon 440
	HEPA Filter	99.9995 % @ 0.12 micron; 550 CFM (15.6 m^3/min.) @ 1.5 in. WG.(0.375 Kpa)
	ACF	Activated Carbon Filter Cartridge

GENERAL INFORMATION 1

TABLE 1 - 2 ♦ MDU DETAIL TECHNICAL SPECIFICATIONS - COMPONENTS

SYSTEM / UNIT	*SPECIFICATIONS*	
Shredding Assembly, Reversible	Motor	20 HP - 460/400 VAC/60/50 Hz/3 phase
	Cutting Blades	0.75 inch (1.9 cm) thickness with hooks
	Cutting Screen	Zero Clearance, with 2” (5 cm) hole pattern
	Gear Reducer	TXT8
	Belt	(4) 5VX-900 - 90" (228.6 cm) R.H.
	Belt	(4) 5VX-1060 - 106" (269.2 cm) LH.
Transfer Hopper	Size	2.8 cubic ft. (78.3 liter)
	Sight Glass	7 5/8 in. x 7 5/8 in. (19.36 cm x 19.36 cm) (Qty. 2)
	Photo Sensors	Through - beam type, infrared (Qty. 2)
	Liquid Level Sensor	Capacitive type
	Sight Glass Rinse	1/4 in. NPT with nozzles
Microwave Section	Microwave Housing	20 in. (50.8 cm) O.D.; 304 stainless steel
	Screw	18.50 in. (46.99 cm); 304 stainless steel
	Drive Motor	1 HP - 460/400 VAC/60/50 Hz/3 phase
	Insulation	3 in. (7.62 cm) insulation; rated @ 400 ^{0}F (204 ^{0}C) with 20 MIL PVC cover
	Temperature Sensor	RTD type (Qty. 2)

GENERAL INFORMATION 1

TABLE 1 - 2 ♦ MDU DETAIL TECHNICAL SPECIFICATIONS - COMPONENTS

SYSTEM / UNIT	*SPECIFICATIONS*	
Microwave Generator (Quantity 6)	HF Output Power	1.4 kW
	Output frequency	2,450 MHz
	Electrical Power Requirements	240/220 VAC/60/50 Hz/1 phase
	Power Consumption	2.1 kW
Temperature Holding Section (THS)	Sight Glass	7 5/8 in. x 7 5/8 in. (19.36 cm x 19.36 cm) (Qty. 2)
	Photo Eye Sensors	Through-beam type infrared (Qty. 2)
	Sight glass rinse	1/4 in. N.P.T. with nozzles
	Temperature Sensor	RTD type (Qty. 1)
Treated Waste Discharge Screw (THS Screw)	Pipe Diameter	8.625 in (21.9 cm) O.D.
	Screw Diameter	7.25 in (18.41 cm)
	Flight Length	193 in (490.22 cm)
	Drive Motor	2 HP - 460/400 VAC/60/50 Hz/3 Phase
Built-in Electric Steam Generator	Steam Capacity	208 lb/hr (457 kg/hr)
	Steam Temperature	324 ^{0}F (162 ^{0}C)
	Vessel Volume	12.3 gal (46.5 liters)
	Electrical Power Requirements	460/400 VAC/60/50 Hz/3 phase
	Power Consumption	60 KW

GENERAL INFORMATION 1

TABLE 1 - 2 ♦ MDU DETAIL TECHNICAL SPECIFICATIONS - COMPONENTS

SYSTEM / UNIT	*SPECIFICATIONS*	
Hydraulic System	Oil Capacity	10 gal (38 liters)
	Pump Pressure	1,900 psig (13.1 Mpa) Maximum Operating Pressure
	Electrical Power Requirements	3 HP - 460/400 VAC/60/50 Hz/3 phase
Enclosure Ventilation Fan and Automatic Louvers	Air Capacity	900 CFM (25.5 m^3/min.)
	Size	16 in. (40.64 cm) diameter blade
	Electrical Power Requirements	120 VAC/60/50 Hz/1 phase
Microwave Survey Meter	Operating Ranges	2 mw/cm^2 - 10 mw/cm^2, 100 mw/cm^2
	Power Requirements	2 Alkaline - 9 volt batteries
Water Pump	Electrical Power Requirements	1/2 HP - 115/230 VAC/60/50 Hz/1 phase
	Inlet/Outlet Port	3/4 inch NPT
	Capacity	408 gal/hr (1542 liter/hr) @ 80 psig (552 Kpa)
Additional Components Supplied	Fire Extinguisher	Halon #1211, 13 lb (5.9 kg)
	Soap Dispenser	Antibacterial, 1 Liter
	Utility Table	Lockable Storage Cabinet
	OMM	Technical Document for Operation And Maintenance

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 1 INTRODUCTION

This chapter describes the functional operation of each of the subsystems and equipment of the MDU necessary for achieving medical waste disinfection. Descriptions are arranged in order of operation.

2 - 2 SYSTEM OVERVIEW

The MDU disinfects infectious medical waste through the application of steam and microwave radiation. The infectious material is temporarily held in a waste container(s), which in turn, are emptied into an in-feed hopper via a charging system. The charging system is located at the front of the MDU. The infectious waste is fed to a shredder by the feed arm where it is shredded. The shredded material is conveyed through the microwave section and temperature holding section, respectively for disinfection. The outlet of the temperature holding section protrudes near the back end of the unit and is designed to transport the disinfected waste into waste disposal containers (or compaction units). From there the material can be transported to a local municipal landfill for disposal or to a refuse recycling plant or wherever ordinary household solid waste is disposed.

The MDU is designed to run automatically with a minimum of operator intervention. The MDU components are enclosed in a weather-resistant steel enclosure, and are suitable for an outdoor operation. The MDU is comprised of the following subsystems.

a. Charging System
b. In-feed Hopper & Feed Arm
c. Extraction System
d. Shredder Assembly
e. Transfer Hopper
f. Microwave Section
g. Temperature Holding Section & Discharge Screw

The aforementioned subsystems are described in subsequent paragraphs of this chapter. Please refer to Figure 1-1 graphic illustration to find depiction of the system components and subsection discussed herein.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 3 CHARGING SYSTEM

The charging system is used for loading the infectious waste into the in-feed hopper. This operation is controlled via the Operators Control Panel.

The charging system consists of a hydraulically operated lift assembly and in-feed hopper door (flap) through which the waste container (up to 1 cubic yard or 880 liters) is emptied. The in-feed hopper flap is raised and lowered by two hydraulic cylinders mounted on the MDU roof. A carriage assembly is attached to the hopper flap by means of a connecting rod, which runs inside U-shaped guide rails. The rails are fitted vertically along the front end of the unit. So, as the hopper flap is opened, the carriage raises the waste container. The carriage can be modified to accommodate waste carts supplied by various manufacturers.

The in-feed hopper door (flap) assembly is fitted with two proximity switches, which detect the position of the flap. The flap's position, open or closed, is fed from the respective switch to the Programmable Logic Controller (PLC), which controls the charging operation. As the in-feed hopper flap comes to its fully opened position, the waste container is tipped, allowing the waste to fall into the in-feed hopper. The tipping operation is complete when the flap has reached its maximum opening. Once the waste container has been emptied (waste container fully tipped), the carriage assembly must be moved to its lowest position to ensure that the flap is completely closed and the waste container is down. If the flap is not fully closed, the shredding system will not start. After the waste has been charged into the system and the flap is fully closed, the unit continues automatic operation and the shredding system will operate.

The operating sequence of the charging system commences when the operator acknowledges a system charge request by momentarily pressing the LIFT UP push button switch. The system runs through its pre-charging sequence, and starts the hydraulic power unit operating. The operator's lift up and lift down controls are enabled allowing the operator to charge the system. When the lift reaches the full up position, the flap-open proximity switch is activated, stopping the lift up operation via the PLC. The action of reaching the full up position indicates to the PLC that the waste has been transferred from the container to the hopper. When the lift reaches the full down position, the flap closed proximity switch (30) is activated, stopping the lift down operation via the PLC. If the lift has traveled from the full up position and then to the full down position, the PLC will recognize that the charging operation has been completed and the hydraulic unit will discontinue operation.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 4 IN-FEED HOPPER & FEED ARM

The In-feed Hopper is fitted with a rotating feed arm, located inside the hopper. The feed arm ensures uniform feeding of waste into the shredder blades. On the opposite side of the feed arm motor, there is one proximity switch. The switch detects the position of the feed arm during charging. The feed arm must be positioned so that waste entering the hopper is not restricted. The same switch counts the revolutions of the feed arm as it turns and reverses direction.

The feed arm operating sequence is delayed after charging the MDU allowing the waste to be gravity fed to the shredder. After the delay, the feed arm operation commences. As it turns it encounters resistance due to waste build up. As the resistance increases, the current draw of the motor also increases. When the current draw reaches a certain level, a current relay is actuated signaling the PLC of the high current condition. The PLC in turn stops the feed arm motor, waits five seconds for the motor to stop rotating, and then reverses the motor's direction. The feed arm operates in reverse until excessive resistance is again encountered or the feed arm has rotated in reverse to the six o'clock position. The PLC will then stop the feed arm motor and wait five seconds for the motor to stop rotating.

The process is then repeated when the feed arm is rotating in the forward direction. When the feed arm makes four full revolutions in the forward direction without tripping the current relay, the PLC assumes that the hopper is empty and calls for system charging. The operator cannot feed waste into the MDU unless the PLC determines that the hopper is empty and the MDU is operating properly.

The in-feed hopper is also fitted with four steam injection nozzles and four water spray nozzles. Steam and water are used to prepare the in-fed hopper to receive waste. Steam is used to manually disinfect the in-feed hopper. The hopper walls are thermally insulated to hold in the steam temperature.

When the hopper is empty, and ready for another charge, steam is injected during the charge preparation to fully saturate the hopper area. After the steam is injected and held, water is sprayed into the in-feed hopper to quench the interior and condense the steam. The extraction system then turns on to evacuate the steam from the hopper. This sequence also accomplishes abatement of air borne pathogen emissions from creating an unsafe working environment. This entire decontamination sequence is automatically initiated by the PLC when the MDU is ready to receive another charge of waste. The hydraulic waste charging system will not operate until this sequence is completed. At that point, the operator will hear an alarm and see the LIFT-UP button lamp illuminated, only then will the lift controls function.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 5 EXTRACTION SYSTEM

The Extraction System is used to evacuate steam from the in-feed hopper during the charging sequence. The extraction damper opens a duct to the extraction filter assembly, which draws (extracts) the steam and air from the in-feed hopper prior to and during the waste charging sequence. An inlet damper on the in-feed hopper flap allows outside air to pass into the in-feed hopper thereby evacuating the hopper volume numerous times before the hopper flap is electronically allowed to open.

Operation of the extraction system commences after water is sprayed to quench the hopper. After the water spray is completed, the extraction blower is started. The extraction blower extracts steam and air through the pre-filter, high efficiency particulate air filter (HEPA) and activated carbon filter (ACF), before discharging to atmosphere. The system is designed to achieve over 11 hopper volume air changes before the hopper flap is allowed to open. This feature simulates criteria used in isolation room for highly infectious airborne diseases in hospitals to ensure maximum safety.

After the steam and air has been extracted from the in-feed hopper, the operator's lift controls are enabled, allowing the system to be charged. When the charging sequence is completed and the in-feed hopper flap is fully closed, sensed by the flap-closed proximity switch, the extraction blower is turned off. When the extraction blower is off, the extraction and inlet dampers close.

When the extraction system is in operation, the pressure drop across the HEPA filter is measured by an analog type manometer located near the filter housing. The pressure drop is used to indicate the efficiency of the filter and thereby the amount of contamination that the filter has collected. As the filter becomes progressively more contaminated, the pressure drop across the filter increases. A pre-filter is used to extract moisture from the air. The filters must be replaced when the pressure drop reaches approximately 3 in of WG (0.75 Kpa).

Extraction drain line valves are located beneath the HEPA filter and carbon filter housing. These valves are to be normally closed and only opened daily, to drain liquid from these housings back into the front of the microwave treatment section.

2 - 6 SHREDDER ASSEMBLY

The shredder assembly is fed waste material from the in-feed hopper by the feed arm. The waste is shredded to a size that can be easily conveyed and effectively disinfected.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 6 SHREDDER ASSEMBLY Cont'd

The integral shredding function achieves many benefits over traditional thermal treatment methods:

- Shredding pre-conditions the to ensure that all items, such as suction canisters and other items that can not be effectively treated by traditional autoclaves, are broken apart and all infectious surfaces are exposed to treatment conditions

- Shredded material allows for more efficient heat transfer, therefore the MDU uses substantially less energy than traditional devices

- Create more efficient conditions to enable processing of pathological material

The shredder assembly consists of a rectangular frame housing with cutter shafts employing twin blades (cutting element) and a single speed motor, which drives the cutter shafts in opposite directions via a spur gear. The cutting element is designed to allow the projection of one blade to engage in the recess of the opposite blade, while cutting at the same time. In this way, shredding over the total circumference of the blade is achieved. In order to obtain even shredding over the entire length of the shaft, the blades are offset on the shafts.

A screen is installed beneath the shredder system to control the degree of shredding. If the shredded material is too large to fall through the screen it is forced up, around the sides of the shredder and recycled back through the cutter blades. The material is continually recycled this way until it has been reduced to the size governed by the screen, allowing it to pass through to the rest of the system for treatment.

The shredder is controlled by two different sources. They consist of the high and low photo switches located on the transfer hopper and a current sensing relay, located in the Main Control Cabinet. Since reversing of the shredder is an integral part of the operation, the relay is used to control the shredder (via the PLC) by monitoring the current draw on the shredder motor. If the current draw exceeds the factory set limit of 40 amperes, the shredder will come to a stop. The shredder will then automatically run in reverse enabling the cutter blades to be released. After a short time of running in reverse, the shredder will then come to a stop and resume rotating in the forward direction. The reversing operation also occurs whenever the shredder is starting from a stopped position. If a number of reversals occur in a programmed amount of time, the PLC will automatically shut the shredder down and the system will go to the fault mode. As the material is shredded to its proper size, it falls into the transfer hopper before moving on through the systems.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 7 TRANSFER HOPPER

The transfer hopper is flange mounted between the shredder and the front end of the microwave conveying section. The transfer hopper, which is welded to the microwave section, is used as an intermediate storage for the shredder waste and controls the supply of material to the microwave screw.

The shredder supplies an adequate amount of material for processing in the microwave section. The transfer hopper is fitted with photo switch sensors that provide feedback signals to the PLC, which controls internal timers to prevent false photo switch signaling. The PLC receives and outputs control signals in response to the following conditions.

a. ***Material below Low Level*** - Indicates that there is insufficient material for the proper operation of the microwave section (indicated by the low level photo switch). The shredder will operate but the microwave section (MWS) will stop. If the material stays below low level for a predetermined time, the MWS MATERIAL LEVEL will go to fault.

b. ***Material between Low and High Levels*** - Indicates that there is a sufficient amount of material for proper operation of the microwave segment. Both the shredder and microwave segment operate.

c. ***Material above High Level*** - The shredder will stop when the material remains at high level for a predetermined time. The MWS MATERIAL LEVEL will go to fault after predetermined time.

This control method cycles the shredder, thus the level in the transfer hopper continually fluctuates, providing a proper flow of material to the microwave section.

The transfer hopper is also fitted with a liquid level sensor for detection of an excessive amount of liquid. The sensor is used to ensure that the hopper does not fill up with liquid, which can cause problems during operation. In the event excess liquid is detected, the System warns of impending shut down by flashing the MWS LIQUID LEVEL lamp on the Touch Screen. After a delay, the enunciator warning horn sounds and the system goes to fault.

The transfer hopper is also equipped with a sample entry point located below the shredder to allow the insertion of microbiological test specimens for the testing of disinfection performance.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 – 8 MICROWAVE SECTION (MWS)

The microwave section heats the shredded waste in a continuous operation. Heating is achieved by steam injection and microwave radiation applied as the material passes through the MWS.

2 - 9 STEAM APPLICATION

At a predetermined distance from the transfer hopper, before MWG#1, steam is injected into the MWS by four (4) steam nozzles. Steam is used to maintain the temperature of the waste and provides the proper environment for the microwave energy to perform disinfection.

2 - 10 TEMPERATURE CONTROL & FAULTS

Microwave radiation is introduced along the length of the microwave segment by six (6) microwave generators (MWG). A temperature sensor located between MWG #2 and MWG #3 monitors the MWS Entry Temperature. If low temperature exists for too long a period of time, the MWS Entry Temperature will go to fault. A temperature sensor located between MWG #5 and MWG #6, monitors the temperature of the material as it exits the MWS (MWS Exit Temperature). During system operation the MWS screw speed is determined by the MWS Exit Temperature. If the material temperature is below 203 ^{0}F (95 ^{0}C), the MWS screw will run at 50% full speed.

If the material temperature is 203 ^{0}F (95 ^{0}C) or above, the MWS screw will run at 100% (Full Speed). The MWS Exit Temperature is enabled when MWG #5 is enabled. The MWS Exit Temperature will go to fault after 5 minutes of low temperature only when enabled.

2 - 11 MICROWAVE GENERATORS (MWG)

The MWGs input the microwave energy necessary to maintain the operating temperature above the set-point to ensure waste disinfection. The MWGs are installed in specially designed stainless steel housing, and (together with HF sealing) are bolted onto the wave-guides via the resonance chamber. The control and power supply wires are fitted with plug-in connectors to facilitate service. The MWG's supply 1,400 watts of output power at a frequency of 2,450 MHz. A built-in hour meter indicates the total operating hours of the MWG preheating filament. A radial fan is located inside each MWG housing cools the magnetron tubes. It is important therefore that the air inlet and outlet vents are kept clean to allow proper circulation. Keeping the MDU doors closed will help prevent dirt and dust from fouling the MWG air vents.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 11 MICROWAVE GENERATORS (MWG) Cont'd

An interlock switch is installed on each microwave generators mounting base. This interlock disconnects power to the microwave generator when removed from the operational position.

Each MWG is monitored by a watchdog Timer within its stainless steel housing. If the current draw of a generator is not within a preset range, the system will signal a fault. Should a MWG be out of service, the MWG power and control can be manually switched off at the control cabinet. A minimum of four MWGs must be on for the system to operate.

2 - 12 MWS OPERATION

The MWS operates independently of the charging operation and microwave generation takes place only under the following conditions:

When the microwave screw conveyor has a sufficient amount of material and:

- Microwave Generator (MWG) fan is operating.
- The microwave screw is operating.
- MDU entrance door is closed.

The transfer hopper photo switches must indicate that a sufficient level (supply) of material exists. The MWG fan must be operating before the MWS screw can turn. The fan forces air between the wave-guide and window of each MWG to prevent condensation and sparking.

A proximity switch located at the screw conveyor's gear motor screw shaft, counts the number of revolutions of the screw. After the MWS screw has completed its first revolution (after start-up) steam is pulse injected. After a total of six revolutions, the first microwave generator (MWG) will turn on (become enabled). At this time steam injection changes to a continuous injection when the MWS screw is turning and pulse injection when the MWS is off. After two additional revolutions, the second MWG will become enabled. Every second revolution thereafter, the next MWG in turn will become enabled until all selected MWG are on.

After all selected MWG units are enabled (on), the steam injection changes to a pulsed injection, whether the MWS screw is turning or not turning.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 12 MWS OPERATION Cont'd

When the system is selected to perform automatic shutdown, and the transfer hopper signals that \t is empty, shutdown of the MWG's will begin. After five revolutions of the microwave screw, the first MWG will shutdown (become disabled) and the MWS Entry Temperature will be disabled. After one additional revolution, the second MWG will be disabled. After each additional revolution, the next MWG in turn will be disabled until all selected MWG's are off. When all MWG units are disabled (off) the steam injection will turn off for the remainder of the shutdown sequence and the MWS Exit Temperature will be disabled. This shutdown sequence ensures that all waste material is treated before exiting the microwave section and entering the temperature holding section.

The MWG operation is interlocked with the unit's door and each MWG is interlocked with a key type safety switch as a protective measure for personnel safety. Should the door be opened while the system is operating, the MWGs will shutdown and will not restart until the door is closed.

The rest of the system will continue to operate as long as the temperature remains at operational levels. If the door, however, is left open for an extended period, the system temperature will drop, causing the system to go into a fault condition and stop. The door open switch can be over-ridden, to allow for testing and maintenance of the system by qualified personnel.

2 - 13 TEMPERATURE HOLDING SECTION (THS)

The Temperature Holding Section (THS) is the final stage of the disinfection process. The THS consists of two component areas; the hopper and the discharge conveyor.

2 - 14 THS HOPPER

The THS hopper is thermally insulated to prevent internal cooling and is flange mounted to the exit end of the Microwave Section (MWS). As treated material exits the MWS, it falls into the hopper of the Temperature Holding Section (THS). The material is retained in this section as part of the disinfection process and the material, temperature is monitored as part of the control process.

The hopper is also used to compensate for variances in the flow of treated material between the MWS and the THS discharge screw. High and Low level photo sensors mounted in the hopper provide feedback signals to the PLC, which controls internal timers to prevent false photo switch signaling. The PLC in turn outputs control signals in response to the following conditions:

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 14 THS HOPPER Cont'd

a. ***Material below Low Level*** - Indicates that there is insufficient material in the THS hopper. Under this condition the MWS screw conveyor continues to operate but operation of the THS discharge conveyor is temporarily disabled. After a period of time below low level, the system goes to fault.

b. ***Material between Low and High Level*** - Indicates that the hopper level is satisfactory. The MWS conveyor and THS discharge screw conveyor will operate normally.

c. ***Material above High Level*** - Indicates that the THS hopper is full, causing the MWS screw conveyor to stop. If the material remains at high level for a predetermined time, the THS MATERIAL LEVEL will go to fault. When the material level falls below the high-level photo switch, a time delay will allow the MWS screw conveyor to restart. This control method cycles the MWS and THS screw conveyors so that the THS Hopper material level remains relatively constant, during automatic operation, thereby providing a proper flow of discharging material.

2 - 15 THS DISCHARGE CONVEYOR

The THS discharge screw conveyor is mounted to the bottom of the hopper and is supported by a stand that is located outside of the unit. It is used to feed the disinfected waste into the granulator or discharge the disinfected waste from the unit directly into a waste container, which is positioned directly below the outlet.

A temperature sensor is located at the bottom of the THS hopper section just above the entry area to the THS screw conveyor (THS exit temperature). This sensor monitors temperature of the waste in the THS. The THS exit temperature sensor becomes enabled when MWG#6 is enabled. The temperature must be 95°C or greater. If the temperature stays below 95°C for five minutes, the THS exit temperature will go to fault.

The bottom portion of the THS discharge conveyor is insulated to protect personnel from bums that can occur due to the high -internal temperatures. The upper portion is not insulated to condense any residual steam and allow the material to cool down before it exits the conveyor.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 – 16 AUXILIARY EQUIPMENT

The MDU auxiliary equipment consists of separate items that perform specific functions in support of the waste disinfection process. The following paragraphs describe this equipment.

2 – 17 STEAM GENERATOR

The PLC monitors the steam generator and determines its operating status. Upon automatic start-up, the steam generator begins to warm up. When the steam temperature reaches 150 ^{0}C the PLC starts the system. If this temperature is not reached within several minutes, the system will go to fault. If the steam temperature drops below 150 ^{0}C and does not recover after a period of time, the system goes into "sleep mode". In the "sleep mode" the system is automatically stopped to allow the steam generator time to recover (steam generator remains ON). When the system is in sleep mode, the PLC waits for the steam temperature to reach 150 ^{0}C before returning the system to automatic operation. This assures that the steam generator has built up a sufficient supply of steam. If this temperature is not reached after several minutes, the system will go to fault.

2 – 18 HYDRAULIC UNIT

The hydraulic unit is used for operating the charging system. The unit is completely self-contained consisting of a pump, reservoir and solenoid valves.

2 – 19 WATER PUMP & WINDOW SPRAY

The water pump supplies water at low pressure to the spray nozzles located at the in-feed hopper and over each viewing glass in both the transfer and THS hopper. At the in-feed hopper, water is sprayed during the charge preparation sequence to quench the hopper's interior and condense steam that was previously injected. At the transfer and THS hoppers, water spray is used to wash away material so that the photo switches have an unrestricted path through the viewing windows, thereby allowing proper operational control. The PLC engages the water pump and spray valve under the following conditions:

a. When the viewing glass is blocked due to high level of material in the transfer hopper.

b. At the transfer hopper, water is sprayed on the viewing glass every three revolutions of the MWS screw. This ensures that the photo switches are always reading the correct material level.

c. Whenever the SPRAY push button is pressed on the Main Control Cabinet. The switch must be released and pressed a second time to produce another spray.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 – 20 VENTILATION SYSTEM

The MDU ventilation system is comprised of a thermostatically controlled fan with mechanical louvers at the discharge end of the MDU, and a motor driven louver, located at the charging end of the unit. Both sets of louvers, open and close, as the fan turns on and off, automatically drawing air through the MDU.

Since power for the ventilation system is always on, it may not be unusual for the fan to turn on by itself even though the system is not operating. The thermostat is located on the same wall as the extraction filter and has been factory preset to operate at approximately 80 ^{0}F (26.6 ^{0}C).

2 – 21 INTERIOR LIGHTS

There are three types of fluorescent light fixtures attached to the ceiling of the unit. They consist of a single 40-watt fixture located next to the in-feed hopper (man door Side), a double 96-watt fixture located over the length of the MWS and a double 40-watt fixture located next to the in-feed hopper (shredder motor side). A light switch is conveniently located at the entrance door, inside the shelter.

2 – 22 DOOR OPEN OVER-RIDE SWITCH

The door open over-ride switch is a key-type switch located next to the interior light switch. The over-ride switch allows trained personnel to operate the system, with the door open while the MWGs are operating. The switch is used for maintenance purposes only and should not be used during normal system operation. It is important that the switch be turned off to assure safety of personnel.

2 – 23 OUTLET RECEPTACLES

The MDU is fitted with ground fault interrupt type, duplex outlet receptacles. They consist of the following:

a. Three brown outlets, for space heaters (15 amps).

b. Two duplex outlets with ground fault protection, located inside the MDU for general use

c. Two duplex outlets with Ground Fault Protection, located outside the MDU for general use.

SYSTEM DESCRIPTION & PROCESS CONTROL 2

2 - 24 POWER DISTRIBUTION PANEL

The distribution panel is located to the right of the Main Control Cabinet and houses circuit breakers for all 120VAC devices. A circuit breaker panel, located above the distribution panel, serves as a disconnect switch and protection device for the distribution panel.

SYSTEM PERFOMANCE 3

The SANITEC MDU has been one of the most scientifically challenged and tested technologies available on the world market. Testing has been successfully performed for many individual states in the US and for many countries around the world, including the UK, Japan, France, Germany and others. The document presents a summary of information. Copies of actual test studies and reports can be made available upon request.

3– 1 MICROBIOLOIGICAL TESTING & RESULTS

The most challenging and comprehensive testing ever performed were for the New York State Department of Health in the US. This test required the processing of microbiological samples from all microbiological categories in order to prove successful efficacy. These particular testing methodology ultimately become the forerunner of the first STAATT guideline published for the evaluation of medical waste treatment technologies:

Organism	*ATCC Strain*	*Colony Count*	*Results*
Bacteria			
Bacillus Subtilis	**6633**	**6.0 Log 7**	**No Growth**
Pseudomonas Aeruginosa	**27317**	**1.5 Log 8**	**No Growth**
Staphlococcus Aureus	**25923**	**1.2 Log 8**	**No Growth**
Enterococcus Faecalis	**19433**	**1.2 Log 8**	**No Growth**
Nocardia Asteroides	**31531**	**1.0 Log 8**	**No Growth**
Fungi			
Candida Albicans	**14053**	**1.2 Log 8**	**No Growth**
Aspergillus Fumigatus	**1022**	**1.1 Log 8**	**No Growth**
Myco-bacteria			
Mycobacterium Bovis	**35737**	**5.0 Log 7**	**No Growth**
Mycobacterium Fortuitum	**35755**	**5.0 Log 7**	**No Growth**
Protozoa			
Giardia Miura	**Cleveland State Univ.**	**1.0 Log 3**	**No Growth**
Virus			
Duck Hepatitis	**Stanford Univ.**	**5.0 Log 7**	**Negative**

Source: North American Laboratory / Stanford University

SYSTEM PERFORMANCE 3

3 – 1 MICROBIOLOIGICAL TESTING & RESULTS Cont'd

The SANITEC MDU has also been tested and approved for use in ***treating pathogical waste*** and for animal carcassess. MDUs owned and operated by SANITEC in California and North Carolina are prcessing pathological wastes. Acceptance and approval for treatment of pathological waste with SANITEC MDUs have been in practice in other areas such as New York State, Texas, Oklahoma, Kansas, Brazil, the Philippines and others.

Of particular note is the testing performed by the State of North Carolina Department of Agriculture specially for the pursoes of treating avain flu contaminated carcasses:

Washington, DC—Embargoed for release, May 8, 2006, 8:00AM EST—Sanitec Industries, Inc. (www.sanitecindustries.com) — On a far corner of North Carolina State University's sprawling Animal & Poultry Waste Management Center, federal and state emergency management officials and microbiologists in protective coveralls watched and waited as equipment inside a Ferrari red tractor trailer churned through a crucial test in what is expected to be an all out assault to contain an outbreak of Avian Flu should it reach the United States.

"The test at NC State confirmed for federal and state officials what thousands of hospitals and health care facilities across the country already know, that the Sanitec system is an effective and environmentally friendly solution to the problem of disposing of bio hazardous waste," said Russell Firestone, Executive Vice President of Sanitec Industries.

Designed to exceed the requirements of an H5N1 outbreak within a large scale poultry plant, the March 15th test, the results of which were released today, involved processing tissue samples infused with Salmonella bacteria and a type of bacterial spore related to Anthrax along with over 2,000 lbs of turkey carcasses.

"In the event of a foreign animal disease (FAD) outbreak in livestock or poultry it will be critical to respond quickly and in a bio-secure manner. Often this is accomplished using depopulation and disposal as the primary means of disease control and eradication," according to Dr. Bethany Grohs, a veterinarian with the U.S. Environmental Protection Agency's Office of Emergency Management. "Sanitec's self-contained, mobile system for carcass disposal is an important tool to have in the emergency response tool kit. Sanitec's mobile system can be brought on-site, thus reducing the risk of disease spread via animal transport and a self-contained system reduces the risk of environmental contamination," said Dr. Grohs, who responded to the 2001 outbreak of Foot-and-Mouth Disease (FMD) in the United Kingdom as well as the U.S. Capitol Hill Anthrax Incident.

SYSTEM PERFORMANCE 3

3 – 2 ENVIRONMENTAL PERFORMANCE – Air Emissions

The SANITEC MDU processes infectious waste at temperatures hot enough to inactivate microbiological organisms, but not to a level where harmful by-products are created. In devices that operate at temperatures above the melting point of plastics, volatile organic compounds (VOC) emissions are a concern. The MDU operates at tempertures far below this point and therefore does not emit harmful air emissions. Actually, tests were performed on six different SANITEC installations analysing air samples with a gas chromoatograph and mass spectrometer for VOC and toxic organic compounds (TOC). Since the MDU is equipped with ACF that could absorb organic emissions, the test was conducted *without the ACF* to prove that the MDU does create emissions from processing. In each case, the MDUs performance was outstanding with results reported below dectable limits (BDL) or far far below personal exposure limits (PEL):

SANITEC VOC TEST RESULTS - TABLE 3

Compound	TLV/PEL (PPM)	Burlington County Hospital Max Conc. (PPM)	Burlington County Hospital Max Conc. "8-Hour"	JFK Medical Center Max Conc. (PPM)	JFK Medical Center Max Conc. "8-Hour"	Our Lady of Lourdes Max Conc. (PPM)	Our Lady of Lourdes Max Conc. "8-Hour"
Benzene	1	0.0074	0.016	BDL	BDL	BOL	BDL
Carbon Tetrachloride	2	0.003	0.0065	BDL	BDL	BDL	BDL
Chloroform	2	0.091	0.197	0.021	0.028	0.073	0.095
Dioxane	2.5	0.037	0.061	BDL	BDL	BOL	BDL
Ethylencimine	0.5	BDL	BDL	BDL	BDL	BDL	BDL
Ethylene Dibromide	20	BDL	BDL	BDL	BDL	BDL	BDL
Ethylene dichloride	1	0.051	0.097	BDL	BDL	BDL	BDL
Tetrachloroethane	N/A	BOL	BCL	BDL	BDL	BDL	BDL
Tetrachloroethylene	25	0.033	0.063	0.012	0.017	BDL	BDL
Trichloroethane	350	BDL	BDL	EDL	BDL	BDL	BDL
Trichloroethylene	50	BDL	BDL	EDL	BDL	0.33	0.33
MIXTURE TLV		0.219 109	0.219	0.011	0.015	0.044	0.054

Compound	TLV/PEL (PPM)	West Jersey M.C. Max Conc. (PPM)	West Jersey M.C. Max Conc. "8-Hour"	Dover General M.C. Max Conc (PPM)	Dover General M.C. Max Conc. "8-Hour"	Cooper Hospital* Max Conc. (PPM)	Cooper Hospital* Max Conc. "8-Hour"
Benzene	1	0.006	0.009	EDL	BDL	BDL	BDL
Carbon Tetrachloride	2	BDL	BDL	EDL	BOL	BDL	BDL
Chloroform	2	0.045	0.064	0.25	0.435	0.014	0.014
Dioxane	25	BOL	BOL	EDL	BOL	BDL	BOL
Ethylencimine	0.5	BDL	BDL	BOL	BDL	BDL	BOL
Ethylene Dibromide	20	BDL	BDL	BOL	BDL	BDL	BDL
Ethylene dichloride	1	BDL	BDL	BDL	BDL	BOL	BOL
Tetrachloroethane	NIA	BDL	BDL	BDL	BDL	BDL	BOL
Tetrachloroethylene	25	BDL	BDL	BDL	BOL	BDL	BOL
Trichloroethane	350	BDL	BDL	BDL	BDL	BDL	BDL
Trichloroethylene	50	BDL	BDL	BDL	BDL	0.004	0.004
MIXTURE TLV		0.029	0.04	0.125	0.218	0.007	0.007

*Length of test period not available: BDL - Below detection limit; N/A = PEL/TLV not available for the compound

SYSTEM PERFORMANCE 3

3 – 2 ENVIRONMENTAL PERFORMANCE – Treated Solid Waste

Treated waste from SANITEC MDUs has been managed and disposed as ordinary soild waste in every location installed in the US and around the world. Following is a representative analysis performed on treated waste exiting a MDU:

Leachability of Metals (TCLP Test)*

Parameter	*USEPA Allowable Concentration*	*Test Result*
Cadmium	1.0	< 0.015
Lead	5.0	0.11
Barium	100	0.99
Silver	5.0	<0.03
Chromium	5.0	< 0.005
Arsenic	5.0	< 0.0054
Selenium	1.0	0.034
Mercury	0.2	< 0.0002

Proximate Analysis of MDU Processed Material*

Parameter	*Normal Hospital Waste (%)*	*Test Results (%)*
Combustibility	25-94	88.01(1)
Moisture	7.7-10.0	5.04-14
Ash & Noncombustibiles	4.9-15.0	6.95(2)

Notes:

(1) Heat value at 8,800 BTU/lb
(2) Does not include needles and sharps in the noncombustibiles

**Test performed by Technical Services, Inc., Jacksonville, FL*
Reprint by permission of Cross/Tessitore & Associates, Orlando, FL

3 – 3 ENVIRONMENTAL PERFORMANCE – Liquid Effluent

The SANITEC MDU does not discharge any liquid waste. The MDU does not have a need for a sewer connection.

SYSTEM PERFORMANCE 3

3 – 3 ENVIRONMENTAL PERFORMANCE – Microwave Energy Emissions

The microwave generators used in the SANITEC MDU have been tested for safety and leakage, and conform to US regulations governed by the Federal Communications Commission (FCC).

The magnatrons used in the MDU are manufacturered within strict tolerances regulated by the FCC, and UL tested in the same manner as magnatrons used for consumer household microwave ovens.

The OSHA permissable exposure limit is 10 mW/cm^2, which is magnitudes greater than any levels measureed in an MDU. Our leakage standard is *ZERO.* Our manual recommeds perodic testing using a handheld leakage detection meter. If any leakage is detected, the user must only tighten the flange bolts on the MWG mounting to the microwave chamber. We recommend that this flange tightening check be performed routinely or when a leakage of ≥ 0.4 mW/cm^2 is detected. With over 15 years of operating experience, the MDU design has been proven safe.

With over 15 years of a commercial operating track record, SANITEC MDU have never been shutdown or taken out of service for failure to meet treatment or environmental standards and requirements. Some MDUs have been in operation for more 15 years with the same designed and features that have been described in this document.

For any additional needs for information or any questions, please contact:

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ATTACHMENT II.

SANITEC, INC.

FINAL REPORT

SANITEC, INC.
MICROWAVE DISINFECTION SYSTEM

MICROBIOLOGICAL EFFICACY STUDY

FOR

THE NEW YORK STATE DEPARTMENT OF HEALTH
ALTERNATIVE REGULATED MEDICAL WASTE
TREATMENT SYSTEM EVALUATION PROGRAM

CONTENTS

SECTION I

INTRODUCTION

INTRODUCTION/SUMMARY

A. Efficacy testing of the ABB Sanitec Microwave Disinfection System commenced July 1, 1991 and ended August 12, 1991. All testing was performed by an independent, certified laboratory, North American Laboratory Group, (NALG). Dr. Richard Tilton supervised the testing for NALG. NALG conducted all aspects of the microbiological procedures with the exception of the Duck Hepatitis B Virus test protocol which was conducted by Stanford University School of Medicine.

1. Length of Testing: Length of testing (July 1 to August 12, October 4) was due to several factors. First, while most of the selected organisms normally grow within 24-48 hours of inoculation, Mycobacterial cultures required two additional weeks of incubation. Second, due to the high cost of performing Duck HBV testing, we attempted to rectify all problems with the test protocol before conducting the viral portion. Our most difficult organisms proved to be Giardia. The first sample from ATCC did not grow. This delayed testing by several weeks. Further discussion with the Centers for Disease Control on Giardia growth requirements proved somewhat successful. However, after final results on Giardia were submitted to the New York State Department of Health (DOH), the parasitology division of the DOH requested a repeat of the test utilizing Giardia muris. These cysts were provided by Dr. Edward Jarroll, Cleveland State University, Cleveland, Ohio. This portion of the protocol was performed on October 4th. Protocol, results, and operating parameters are located in the "Additional Data"section.

2. Protocol Test Tubes: Finding the appropriate tube to introduce the specimens into the microwave unit took several days. Polyethylene or polypropylene constructed tubes worked best. However, on the first and second days of testing, although most of the samples were retrieved, 30% - 40% lacked fluid. Four types of tubes were evaluated on the third day. Each specimen number included two tubes. Therefore, double the number of usual specimens were run. Both, one, or none of the tubes retained fluid. Only one tube consistently retained fluid. The tube was used throughout the rest of the protocol.

3. Number of Runs:Because of the tube problem, a fourth run was added to increase the number of test organisms and demonstrate reproducibility.

4. Travel time:Travel times (Difference between input time and ejection time) vary with the average being approximately 59 minutes (range 31 - 90 minutes). The difference in travel time can be attributed to several factors., namely waste composition. Although we utilized actual biomedical waste from a hospital, it was not possible to maintain the same waste characteristics for daily testing. The biomedical waste stream varied from large volumes of sharps to large volumes of contaminated dressings and fluid containers. Waste composition was basically different every day.

5. Bacillus Testing: Each test run on July 10th, 11th, and 16th included one group of 10 Bacillus subtilis specimens. This was conducted for the Connecticut efficacy protocol. Results are also included in the laboratory section.

6. Conclusion: The high level of disinfection/sterilization from this data clearly demonstrates the ABB Sanitec Microwave Disinfection System is capable of meeting the parameters set for alternative technologies to treat and destroy biomedical waste as established by the state of New York.

SECTION II

EFFICACY PROTOCOL

ABB Sanitec Microwave Disinfection System
New York Efficacy Protocol

I. Introduction

The ABB Sanitec Microwave Disinfection System is an alternative method for treatment of biomedical waste. Biomedical waste is disinfected and made unrecognizable after being exposed to a process utilizing steam, shredding, and microwaves. The system incorporates computerized control systems to monitor appropriate disinfection levels and safety parameters.

The following protocol describes the materials and methods to determine the efficacy of the Sanitec Microwave Disinfection System in accordance with guidelines provided by the New York State Department Of Health (DOH).

II. Materials

Organisms to be used in this efficacy protocol are listed in Table I. Bacteria, mycobacteria, fungi, and protozoa will be obtained from American Type Culture Collection[1]. Duck Hepatitis B Virus (DHBV) will be provided by Stanford University Medical Center, Stanford, California. The list is comprised of organisms from those suggested by the DOH to be used in studies of the efficacy of alternative regulated waste management systems for approval by the Commissioner of Health.

Table I

	ATCC Strain
A. Bacterial	
1. Bacillus subtilis (spores)	6633
2. Enterococcus faecalis	19433
3. Pseudomonas aeruginosa	27317
4. Staphylococcus aureus	25923
5. Nocardia species	31531
B. Mycobacterial species	
1. Mycobacterium bovis	35737
2. Mycobacterium fortuitum	35755
C. Fungi	
1. Candida albicans	14053
2. Aspergillus fumigatus	1022
D. Protozoa	
1. Giardia intestinalis	50114
E. Virus	
1. Duck Hepatitis B Virus (DHBV)	Provided by Stanford University

III. Methods

A. General:

The methodology will involve:

1. Preparation of test samples by North American Laboratory Group, New Britain, Connecticut.

2. Transportation of specimens to Safe Way Disposal Systems, Middletown Connecticut where the test samples will be introduced into a Sanitec Microwave unit.

3. Subsequent transportation of test samples back to North American Laboratory Group for microbial culturing.

Note 1: Travel time between facilities is 30-40 minutes.

B. Sample preparation

1. Test samples will be prepared as recommended by supplier[2] using standard microbiological technique[3]. Each bacterial, mycobacterial, and fungal species will be grown on standard culture media - e.g., 5 % sheep blood agar (Becton Dickinson Microbiology Systems, Cockeysville, Md.), Middlebrook 7H10 agar and Lowenstein-Jensen medium, Gruft modification (Becton Dickinson), and Sabouraud's Dextrose Agar (Becton Dickinson), respectively. After sufficient growth has occurred for each test organism, the surface of the agar medium will be washed with sterile physiological saline and suspensions prepared equivalent by optical density 0.5 McFarland standard and confirmed by plate count to approximately 1×10^6 - 1×10^8 colony forming units per ml (cfu/ml).

Note : Formulation for specific media found under Appendix III.

2. One (1) ml of the test organism (1×10^6 - 1×10^8 cfu/ml) will be placed into plastic vials. Vials will be placed in numbered orange colored cloth sacks to facilitate retrieval after treatment.

Note 1: Giardia intestinalis samples will be prepared and tested according to protocol in Appendix I.

Note 2: DHBV samples will be initially prepared at Stanford University School of Medicine and delivered to North American Laboratory Group to complete sample preparation. (See Appendix II for specific DHBV testing protocol.)

3. Eighteen samples will be prepared for each test organism.

   a. Fifteen (15) test samples
   b. Three (3) positive control

4. Test samples will be divided into lots of three, i.e., five (5) test samples and one (1) positive control/lot. Each lot will be tested on different days.

C. Sample Transportation

1. Samples prepared for testing will be immediately put on ice (4°C) and transported to the test site (Safe Way Disposal Systems, 90 Industrial Park Road, Middletown, Connecticut).

D. Sample Treatment

1. Test samples will be processed in the Sanitec unit currently in operating at Safe Way Disposal Systems. Samples will be processed along with biomedical waste generated by hospitals during normal operating hours and conditions.

2. Operating parameters

a. Capacity:

250 kg/hr ((550 lbs./hr)

b. Temperature and Time:

The average temperature of the infeed waste should be not less than 0°C (32°F).

The input steam temperature should not be less than 150°C (300°F).

The Microwave Section (MWS) inlet temperature should be not less than 95°C (203°F).
The Temperature Holding section (THS) exit temperature should be not less than 95°C (203°F).

To ensure proper conditions for disinfection, the unit control system is designed to monitor and control exit temperature by means of a speed control on the conveyor to allow adequate residence time (30 minutes) for the waste to reach the desired temperature. The unit is equipped with a strip chart recorder such that proper monitoring of operating conditions and records are maintained by recording the MWS inlet temperature and speed (rpm) of the MWS conveyor.

3. Samples will be allowed to come to room temperature before processing.

4. Each organism to be tested will be run in lots as indicated under "Sample preparation". Six (6) consecutive samples will be introduced into the unit. There will be a lag time of thirty (30) seconds between introduction of each sample. Data to be collected is described below.

5. Test organisms will be inserted through a sample port located below the shredder knives of the Sanitec unit, and allowed to traverse the full cycle of the microwave disinfection process. The test samples will be allowed to drop freely from the Sanitec unit discharge conveyor, into a dumpster along with treated biomedical waste routinely processed at the hospital.

6. Positive control samples will be handled in the same manner as the test samples with the exception of not being introduced into the Sanitec unit. Positive controls will be placed on ice when the last test sample for the appropriate organism is retrieved.

7. During the processing of the test samples in the Sanitec unit the following data will be recorded:

   a. Sample insertion time
   b. Microwave treatment section inlet temperature
   c. Microwave treatment section outlet temperature
   d. Discharge section outlet temperature
   e. Sample retrieval time

8. Test samples will be retrieved, placed on ice (4°C), and immediately transported back to North American Laboratory Group for microbial testing.

E. Sample Testing

1. Upon receipt of the treated test samples by North American Laboratory Group, vials will be allowed to reach room temperature, aseptically opened and 0.1 ml of fluid inoculated directly onto appropriate growth media and incubated. The remainder of the contents (0.9 ml) will be transferred into a tube of growth media and also incubated. Growth media and incubation conditions to be used for each of the test organism are listed in Table 2.

Table 2

Test Organisms	Growth Media	Incubation Temp.	Incubation Time
Bacterial (For Nocardia, see fungal media)	BAP* BHI* broth	35°C	7 days
Mycobacterial species	MB* 7H11 MB* 7H9 broth (7H12 medium)	35°C - 37°C	4-6weeks
Fungi	Sab* Dextrose agar Sab* Dextrose broth	30°C	7 days
Protozoa	See Appendix I for protocol		
Virus	See Appendix II for protocol		

* BAP - Blood Agar Plate
BHI - Brain Heart Infusion
MB - Middlebrook
Sab - Sabouraud

3. Any positive growth will be subcultured to appropriate media (based on type of test sample) to determine contamination (false positive) or true positive.

4. At the end of the incubation period, each tube will be subcultured to the requisite growth media and incubated for:

72 hours	-	(bacterial and fungal species)
2-4 weeks	-	(mycobacterial)

IV. Data Evaluation

A. Results

1. The Sanitec Microwave process is described as "disinfection." Therefore, acceptable results for bacterial, mycobacterial, and fungal organisms would be to achieve a reduction in the original concentration of organisms by a factor of $1 \times 10^3 - 10^4$ cfu/ml.

2. Acceptable results for parasites would be a reduction in the number of cysts /ml by a factor of 1×10^2 cysts/ml.

3. Acceptable results for DHBV would be negative results in all test sample procedures. See Appendix II for specific test results.

B. Reports

1. Upon completion of efficacy testing , all data recorded during the test sample preparation, testing, and culturing will be analyzed. Final analysis and all data will be submitted to the New York State DOH for efficacy evaluation.

V. Safety

A. Trained personnel will be monitoring the Sanitec unit during efficacy operations. All personnel will be instructed in appropriate safety guidelines to include but not be limited to universal precautions, electrical safety, and microwave safety.

B. Microwave leakage will be checked on a daily basis to ensure the rate remains below OSHA PEL (10 mW/cm^2). Leakage rates should normally be zero. On occasion, from ABB's experience, levels have measured 1.0 mW/cm^2. The magnetrons used in the ABB Sanitec systems have power output of 1.2 kw at 2,450 Hz which is the equivalent of two consumer household microwave ovens. Therefore the ABB Sanitec systems should not be considered as an enormous or usually high user of microwave energy.

Appendix I

Protozoa Testing Protocol
Giardia intestinalis

I. Material

1. Giardia intestinalis, supplied by ATCC, strain 50114

Note: See Appendix III for specific growth media recommended by ATCC

II. Methods

1. Samples will be prepared by North American Laboratory Group. Vials will contain one (1) ml of a concentration equivalent to 1 x 10^4-10^6 cysts/ml. Cysts will be counted on a hemacytometer to verify concentration.

2. Twelve samples will be prepared:
   a. Nine (9) test samples
   b. Three (3) positive controls

3. Test samples will be divided into lots of three, i.e., three (3) test samples and one (1) positive control/lot. Each lot will be tested on different days.

4. Samples will be processed as indicated in Part III, Methods, Section b, Sample Preparation, subpart 4.

5. Upon receipt of Giardia samples at North American Laboratory Group, a direct microscopic examination and cell count, using hemacytometer, will be performed on the specimens.

6. 0.5 ml of specimen will be added to growth media and incubated at 35°C for 5 days to allow for cyst maturation.

7. Cysts will then be resuspended in 0.5 ml of fresh growth medium, and depression slides filled with the suspension. The slides will be coverslipped, sealed with Vaseline-paraffin and incubated for 1 hour at 37°C. After incubation, the number of cysts will be counted and tested for viability by eosin exclusion. Survival fraction of each sample will be computed relative to viability in controls arbitrarily designated to be 100%.

Appendix II

Hepadnavirus Test Protocol
Duck Hepatitis B Virus

I. Material

1. Duck Hepatitis B Virus - DHBV[4]
   Provided by Patricia L. Marion, Ph.D.
   Sr. Research Scientist
   Stanford University School of Medicine
   Department of Medicine
   Division of Infectious Disease
   Stanford, California

II. Methods

1. 5 samples will be prepared for the efficacy protocol by Stanford University. Vials will contain 1 ml each of a standard inoculum with a titer of 1×10^6 infectious doses per ml. (2 vials - positive controls, 3 vials - test samples). Two lots, one containing one (1) positive control and one (1) test sample, the second containing one (1) positive control and two (2) test samples will be run on different days.

2. Specimens will be frozen at Stanford University , packed in dry ice, and transported via Federal Express to North American Laboratory Group, New Britain, Connecticut.

3. Specimens will be kept frozen upon arrival to North American Laboratory Group. Specimens will be brought to room temperature prior to placing them into orange colored cloth sacks. Specimens will then be processed as indicated Part III, Methods, section B, Sample preparation, subpart 4.

4. Upon receipt DHBV samples at North American Laboratory Group after treatment, test vials will be frozen, packed in dry ice, and returned to Stanford University School of Medicine via Federal Express for further evaluation.

5. At Stanford, specimens will be allowed to thaw and reach room temperature. At such time, samples will be diluted in sterile phosphate-buffered saline supplemented with 1% bovine serum albumin by 10 fold increments to a final dilution of 10^{10}. One tenth (.1) ml of each dilution will be injected intramuscularly into three (3) newly hatched ducklings, whose blood will be drawn prior to injection. Blood samples will be taken from the ducklings at 1, 2, and 3 weeks after injection. The animals will be sacrificed at 3 weeks and the livers frozen. Sera will be tested for evidence of viremia using slot blots, as described in Cheung et al (1989)[5,6]. If all sera from an injected animal are negative for viremia, DNA will be extracted from the liver and tested for the presence of viral sequences by blot hybridization and confirmed by Southern hydridization (Marion et al, 1984 and 1987)[7,8].

III. Results

1. Acceptable results for DHBV will be

a. No evidence of viremia using slot blots
b. No DNA viral sequences in liver extractions by blot hybridization or Southern hybridization

Appendix III

Media
(As recommended by ATCC[9] for initial isolation of their products)

Table I

A. Bacterial	ATCC Strain	Media (Agar)
1. Bacillus subtilis (spores)	6633	Nutrient
2. Enterococcus faecalis	19433	Brain Heart Infusion
3. Pseudomonas aeruginosa	27317	Trypticase Soy
4. Staphylococcus aureus	25923	Blood
5. Nocardia species	31531	Yeast Malt Extract
B. Mycobacterial species		
1. Mycobacterium bovis	35737	Middlebrook or
2. Mycobacterium fortuitum	35755	Lowenstein-Jensen
C. Fungi		
1. Candida albicans	14053	YM
2. Aspergillus fumigatus	1022	Malt Extract Agar
D. Protozoa		
1. Giardia intestinalis	50114	Keister's Modified TYI-S-33 Medium

References

1. American Type Culture Collection - Catalogue of Bacteria and Phages
   American Type Culture Collection - Catalogue of Fungi
   American Type Culture Collection - Catalogue of Protozoa
   12301 Parklawn Drive
   Rockville, Maryland 20852-1776

2. Ibid.1.

3. Manual of Clinical Microbiology, 5th Edition, 1991. Section IV. Bacteria, Section V. Fungi, A. Balows, W.J. Hausler, Jr., K.L. Hermann, H.D. Isenberg, H.J. Shadomy. American Society for Microbiology, Washington, D.C.

4. Use of Animal Models to Study Hepatitis B Virus, Patricia L. Marion, Progress in Medical Virology, Vol. 35, pp. 43-75 (Karger, Basel 1988).

5. Epitope Mapping of Neutralizing Monoclonal Antibodies against Duck Hepatitis B Virus, R.C. Cheung, et al, Journal of Virology, Vol. 632, No. 6, pp. 2445-2451.

6. Epitope - Specific Antibody Responses to the Surface Antigen of Duck Hepatitis B Virus in Infected Ducks, R.C. Cheung, et al, Virology, Vol. 176, pp. 546-552, 1990.

7. Liver disease associated with duck hepatitis B Virus infection of domestic clucks. P.L. Marion, et al, Proceedings National Academy of Science, Vol. 81, pp 898-902, February 1984.

8. Experimental Transmission of Duck Hepatitis B Virus to Pekin Ducks and to Domestic Geese, P.L. Marion, et al, hepatology, Vol. 7, No.4, pp. 724-731, 1987.

9. Ibid 1.

SECTION III

LABORATORY RESULTS

A. NORTH AMERICAN LABORATORY GROUP

1. NEW YORK
2. CONNECTICUT

B. STANFORD UNIVERSITY SCHOOL OF MEDICINE

NORTH AMERICAN LABORATORY GROUP

1 Lake Street
New Britain, CT
06052
203-826-1140

September 3, 1991

TO: Mr. Ed Krisiunas
Safeway, Inc.

FROM: Dr. Richard C. Tilton
North American Laboratory Group

FINAL REPORT - Evaluation of ABB Microwave Medical Waste Disposal Unit

1. Following is the final report for New York State.

Dr. Richard C. Tilton

RCT:gmc
enclosures

Initial Processing

A. The following isolates were processed from the ATCC

Bacillus subtilis	ATCC	6633
Ps. aeruginosa	ATCC	27317
Staph. aureus	ATCC	25923
Aspergillus	ATCC	1022
Candida albicans	ATCC	14053
Nocardia asteroides	ATCC	31531
Enterococcus faecalis	ATCC	19433
Giardia lamblia	ATCC	50114
Mycobacterium bovis	ATCC	35737
M. fortuitum	ATCC	35755

B. All isolates were transferred 2x and a suspension made in the appropriate liquid medium. The suspension was adjusted to 1 x 10^8 cfu/ml. All broth cultures were diluted (serial 10 fold dilutions) to 1 x 10^3 cfu per ml and plated in order to calibrate the initial colony count at 1 x 10^5-10^6 cfu per ml.

Isolate	Actual Control Inoculum
B. subtilis	6.0 x 10^7
P. aeruginosa	1.50 x 10^8
St. aureus	1.20 x 10^8
Aspergillus	1.10 x 10^8
C. albicans	1.20 x 10^8
Nocardia	1.00 x 10^8
Enterococcus	1.20 x 10^8
M. bovis	5.0 $\pm$ x 10^7
M. fortuitum	5.0 $\pm$ x 10^7

C. All inocula were freshly prepared and diluted to an approximate concentration of 10^6 cfu/ml. This was usually accomplished by a 1:100 dilution of a McFarland 0.5 standardized inoculum. The McFarland standard was calibrated by nephelometry.

D. Inocula was prepared in sterile screw capped tubes on the day of the experiment and transported on ice to the facility. All tubes including controls were returned to the lab for subculture by 4 p.m.

E. All processed tubes were subcultured to solid media and BHI broth and incubated as follows before being designated as "No Growth".

	Agar	Broth
B. subtilis	- 7 days	72 hours
Ps. aeruginosa	- 7 days	72 hours
Staph. aureus	- 7 days	72 hours
Enterococcus	- 7 days	72 hours
Nocardia	- 7 days	72 hours
Aspergillus	- 7 days	72 hours
Myco. bovis	- 4 weeks	2 weeks
Myco. fortuitum	- 4 weeks	2 weeks
Candida	- 7 days	2 weeks

F. Empty = Contents of vial lost in unit

Missing = Vial not recovered from unit

Crushed = Vial crushed and contents unusable

G. All subcultures are "final".

H. The Giardia results are included at the end of the results on bacteria, fungi, and Mycobacterium.

Date of Run: 7-1-91

Isolate	Tube #	Result
B. subtilis	1	1.75×10^2 - g + rods
	2	1.50×10^2 - g + rods
	3	empty
	4	NG
	5	empty
	Control	3×10^6 (inoc. too high)
Ps. aeruginosa	1	NG
	2	empty
	3	NG
	4	empty
	5	NG
	Control	2×10^6
Staph. aureus	1	NG
	2	NG
	3	missing
	4	NG
	5	empty
	Control	2×10^6
Aspergillus	1	empty
	2	NG
	3	NG (2 wks)
	4	NG (2 wks)
	5	empty
	Control	Growth - 1 wk
Candida	1	empty
	2	NG
	3	empty
	4	NG (72 hrs)
	5	empty
	Control	2×10^6 (48 hrs)
Nocardia	1	NG
	2	empty
	3	NG
	4	empty
	5	missing
	Control	1.2×10^6 (48 hrs)

Enterococcus	1	empty
	2	NG
	3	NG
	4	missing
	5	NG
	Control	2.0×10^6
Mycobacterium bovis	1	NG
* processed 7/10/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 colonies/0.1 ml AFB smear - Pos
M. fortuitum	1	NG
* processed 7/10/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 colonies/0.1 ml AFB smear - Pos

Date of Run: 7-2-91

B. subtilis	1	NG
	2	empty
	3	crushed
	4	crushed
	5	empty
	Control	8.5×10^5
Ps. aeruginosa	1	empty
	2	NG
	3	empty
	4	empty
	5	NG
	Control	1.10×10^6
Staph. aureus	1	NG
	2	NG
	3	missing
	4	NG
	5	NG
	Control	1.0×10^6
Aspergillus	1	NG
	2	empty
	3	empty
	4	empty
	5	empty
	Control	Growth (1 wk)
Candida	1	NG
	2	NG
	3	NG
	4	NG
	5	empty
	Control	9.5×10^5
Nocardia	1	NG
	2	NG
	3	missing
	4	NG
	5	missing
	Control	9.0×10^5 (48 hrs)

Enterococcus	1	empty
	2	empty
	3	empty
	4	NG
	5	empty
	Control	1.10×10^6
Mycobacterium bovis	1	NG
* processed 7/11/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 colonies/0.1 ml AFB smear - Pos
M. fortuitum	1	NG
* processed 7/11/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 colonies/0.1 ml AFB smear - Pos

Date of Run: 7-3-91

Isolate	Tube #			
B. subtilis	1	NG	6	NG
	2	empty	7	empty
	3	NG	8	NG*
	4	empty	9	NG
	5	NG	10	NG
			Control	1×10^6
Ps. aeruginosa	1	NG	6	empty
	2	NG	7	empty
	3	NG	8	empty
	4	NG	9	empty
	5	empty	10	NG
			Control	1.15×10^6
Staph. aureus	1	NG	6	NG
	2	NG	7	NG
	3	NG	8	NG
	4	NG	9	empty
	5	NG	10	empty
			Control	1.10×10^6
Aspergillus	1	empty	6	NG
	2	NG	7	NG
	3	NG	8	NG
	4	NG	9	empty
	5	empty	10	NG
			Control	Growth - 1 wk
Candida	1	empty	6	NG*
	2	empty	7	NG
	3	NG	8	NG
	4	NG	9	empty
	5	empty	10	NG
			Control	9×10^5
Nocardia	1	empty	6	NG
	2	NG	7	NG
	3	NG	8	NG
	4	NG	9	empty
	5	empty	10	NG
			Control	9.5×10^5

* small amount left

Enterococcus	1 NG	6 NG
	2 NG	7 empty
	3 NG	8 NG
	4 NG	9 NG
	5 NG	10 NG
		Control 1 x 10^6
Mycobacterium bovis	1	NG
* processed 7/16/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 col/0.1 ml AFB smear - Pos
M. fortuitum	1	NG
* processed 7/16/91	2	NG
	3	NG
	4	NG
	5	NG
	Control	>50 col/0.1 ml AFB smear - Pos

The 7-3-91 run was a double run using 2 types of tubes, that is 10 tubes/isolate. In some cases such as Candida, Staph., and Pseudomonas, both large and small tubes of a replicate set were empty.

Date of Run: 7-16-91 Repeat Cultures

Isolate	Tube #	Result
B. subtilis	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - 1×10^6
Ps. aeruginosa	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - 1×10^6
Staph. aureus	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - 1.0×10^6
Aspergillus	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - Growth
Candida	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - 9×10^5
Nocardia	1	
	2	All tubes (1-5)
	3	No growth
	4	
	5	Control - 9×10^5

Enterococcus	1	NG
	2	NG
	3	empty
	4	NG
	5	NG
		Control ~ 9.5×10^5

* All Gram stains of controls were positive for control organism

1. A culture of Giardia lamblia ATCC 50114 was received and re-cultured in Keister's media. Cultures were incubated at 37 C and checked daily for motile organisms. Approximately 20-25 motile trophs of Giardia per 1pf were seen on Day 3.

2. Giardia were tested on 3 occasions at Safeway 8/8, 8/9, 8/12. Data is as follows:

Date - 8/8

Control - motile organisms seen upon return from Safeway (10 1 pf)*
tubes 1-5 - no motile organisms observed after processing.

Date - 8/9

Control - motile organisms seen upon return from Safeway (10 1 pf)
Tubes 1-5 - no motile organisms observed after processing.
Tube #4 was empty on return from Safeway and tubes 1 and 2 only had a few drops in them.

Date - 8/12

Control - motile organisms seen upon return from Safeway (10 1 pf)
Tubes 1-10 - no motile organisms observed after processing.

All tubes were subcultured to fresh broth and both original tubes and subculture were incubated at 37 C for 7 days.

No motile organisms were observed in any original or subcultured tube.

Control tubes after 7 days incubation were exmined. Giardia trophs were observed but motility was very sluggish.

* Fewer organisms were observed in the "processed" control as viable organisms were observed stuck to the sides of the plastic tube.

1 Lake Street
New Britain, CT
06052
203-826-1140

August 20, 1991

TO: Mr. Ed Krisiunas
Safeway, Inc.

FROM: Dr. Richard C. Tilton
North American Laboratory Group

FINAL REPORT - Evaluation of ABB Microwave Medical Waste Disposal Unit

1. Following is the final report for Connecticut.

Dr. Richard C. Tilton

RCT:gmc
enclosures

Contras/Initial Processing

A. The following isolate was processed from the ATCC

Bacillus subtilis ATCC 6633

B. All isolates were transferred 2x and a suspension made in the appropriate liquid medium. The suspension was adjusted to 1×10^8 cfu/ml. All broth cultures were diluted (serial 10 fold dilutions) to 1×10^3 cfu per ml and plated in order to calibrate the initial colony count at 1×10^5-10^6 cfu per ml.

Isolate	Actual Control Inoculum
B. subtilis	6.0×10^7

C. All inocula were freshly prepared and diluted to an approximate concentration of 10^6 cfu/ml. This was usually accomplished by a 1:100 dilution of a McFarland 0.S standardized inoculum. The McFarland standard was calibrated by nephelometry.

D. Inocula was prepared in sterile screw capped tubes on the day of the experiment and transported on ice to the facility. All tubes including controls were returned to the lab for subculture by 4 p.m.

E. All processed tubes were subcultured to solid media and BHI broth and incubated as follows before being designated as "No Growth".

B. subtilis - initial subculture (agar) - 7 days
broth subculture - 72 hrs.

F. Empty = Contents of vial lost in unit

Missing = Vial not recovered from unit

Crushed = Vial crushed and contents unusable

Date of Processing:	Tube #	B. subtilis Results (7 days agar) 72 hr - broth)
7-10-91	1	No growth
	2	No growth
	3	No growth
	4	No growth
	5	No growth
	6	No growth
	7	No growth
	8	No growth
	9	No growth
	10	No growth
	Control	9.5×10^5 cfu/ml
7-11-91	1	No growth
	2	No growth
	3	No growth
	4	No growth
	5	No growth
	6	No growth
	7	No growth
	8	No growth
	9	No growth
	10	No growth
	Control	1×10^6 cfu/ml
7-16-91	1	No growth
	2	No growth
	3	No growth
	4	No growth
	5	No growth
	6	No growth
	7	No growth
	8	No growth
	9	No growth
	10	No growth
	Control	1×10^6 cfu/ml

All agar plates were incubated for 7 days and broth for 72 hrs.

DIVISION OF INFECTIOUS DISEASES
STANFORD UNIVERSITY SCHOOL OF MEDICINE
STANFORD, CALIFORNIA 94305-5107

Patricia L. Marion, Ph.D.
Senior Research Scientist
Infectious Diseases, S-156

Tele. No. 415-725-3939
Fax No. 415-723-2395

November 22, 1991

Edward Krisiunas, MT(ASCP), CIC
Infection Control/Safety Coordinator
Safe Way Disposal Systems, Inc.
90 Industrial Park Road
Middletown, CT 06457

Dear Mr. Krisiunas,

Enclosed is a copy of the final results of the study of decontamination of duck hepatitis B virus by your medical waste disposal system. I am pleased that everyone was satisfied with our efforts and the results. I would like to add that both Irina Cross and Zili Li helped with this project. Zili not only did half the duck work, he also did all the molecular analysis.

We would enjoy having you visit if you are in the area.

Sincerely yours,

Patricia Marion

Patricia L. Marion, Ph.D.

Date of Inoculation: 7-23-91 Sample: Control, Day One

Dilution of DHBV Inoculum	Duck Number	Slot Blot of Sera				Slot Blot of Liver DNA
		Week 0	1	2	3	
10^{-1}	AY223	-	++++	-	-	NA
	AY219	-	++++	-	-	NA
10^{-2}	AY248	-	+	±	±	NA
	AY254	-	-	-	-	++++
10^{-3}	AY282§	-	-	-	+	NA
	AY278§	-	++	+	±	NA
10^{-4}	AY201§	-	-	-	-	NA
	AY250*	++++	++	+++	+++	NA
10^{-5}	AY238	-	-	-	-	+++
	AY229	-	-	-	-	+++
10^{-6}	AY230	-	-	+	-	NA
	AY213	-	-	+	+	NA
10^{-7}	AY216	-	-	++	-	NA
	AY270	-	-	-	-	-
10^{-8}	AY208	-	-	-	-	-
	AY263	-	-	-	-	-

*DHBV positive when hatched (before inoculation of DHBV).

§Duck was raised in same cage with congenitally DHBV-positive duck (*).

NA: Not assayed.

+: DHBV DNA <1 ng/ml.

++: DHBV DNA 1-10 ng/ml.

+++: DHBV DNA 10-100 ng/ml.

++++: DHBV DNA >100 ng/ml.

Date of Inoculation: 7-30-91 Sample: Test One, Day One

Dilution of DHBV Inoculum	Duck Number	Slot Blot of Sera				Slot Blot of Liver DNA
		Week 0	1	2	3	
10^{-1}	BY201 §	-	-	-	-	-
	BY238 §	-	-	-	-	-
10^{-2}	BY250*	++++	+++	+++	+++	NA
	BY267*	++++	+++	+++	+++	NA
10^{-3}	BY281	-	-	-	-	-
	BY229	-	-	-	-	-
10^{-4}	BY213	-	-	-	-	NA
	BY221	-	-	-	-	NA
10^{-5}	BY282 §	-	-	+	++	NA
	BY278*	++++	+++	++	+++	NA
10^{-6}	BY223 §	-	-	-	-	NA
	BY254 §	-	-	-	-	NA
10^{-7}	BY248	-	-	-	-	NA
	BY262	-	-	-	-	NA
10^{-8}	BY259	-	-	-	-	NA
	BY216	-	-	-	-	NA

*DHBV positive when hatched (before inoculation of DHBV).

§Duck was raised in same cage with congenitally DHBV-positive duck (*).

NA: Not assayed.

+: DHBV DNA <1 ng/ml.

++: DHBV DNA 1-10 ng/ml.

+++: DHBV DNA 10-100 ng/ml.

++++: DHBV DNA >100 ng/ml.

Date of Inoculation: 8-06-91 Sample: Test Two, Day One

Dilution of DHBV Inoculum	Duck Number	Slot Blot of Sera				Slot Blot of Liver DNA
		Week 0	1	2	3	
10^{-1}	CY259	-	-	-	-	-
	CY267	-	-	-	-	-
10^{-2}	CY254	-	-	-	-	-
	CY278	-	-	-	-	-
10^{-3}	CY223	-	-	-	-	NA
	CY221	-	-	-	-	NA
10^{-4}	CY270	-	-	-	-	NA
	CY236	-	-	-	-	NA
10^{-5}	CY250	-	-	-	-	NA
	CY224	-	-	-	-	NA
10^{-6}	CY211	-	-	-	-	NA
	CY219	-	-	-	-	NA
10^{-7}	CY181	-	-	-	-	NA
	CY262	-	-	-	-	NA
10^{-8}	CY229	-	-	-	-	NA
	CY216	-	-	-	-	NA

*DHBV positive when hatched (before inoculation of DHBV).

§Duck was raised in same cage with congenitally DHBV-positive duck (*).

NA: Not assayed.

+: DHBV DNA <1 ng/ml.

++: DHBV DNA 1-10 ng/ml.

+++: DHBV DNA 10-100 ng/ml.

++++: DHBV DNA >100 ng/ml.

Date of Inoculation: 8-14-91 Sample: Control, Day Two

Dilution of DHBV Inoculum	Duck Number	Slot Blot of Sera				Slot Blot of Liver DNA
		Week 0	1	2	3	
10^{-1}	DY282	-	++	±	+	NA
	DY263	-	++	+	+	NA
10^{-2}	DY281 #	-	+	-	-	NA
10^{-3}	DY224	-	-	+	-	NA
	DY201	-	-	+	+	NA
10^{-4}	DY250	-	-	±	-	NA
	DY267	-	-	-	-	NA
10^{-5}	DY254	-	-	++	+	NA
	DY229	-	-	+	-	NA
10^{-6}	DY268	-	-	-	-	+++
	DY278	-	-	-	-	+++
10^{-7}	OY219	-	-	-	-	-
	DY262	-	+	-	-	-
10^{-8}	DY248	-	-	-	-	NA
	DY259	-	-	-	-	NA

*DHBV positive when hatched (before inoculation of DHBV).

§Duck was raised in same cage with congenitally DHBV-positive duck (*).

NA: Not assayed.

#Duck died during first week.

+: DHBV DNA <1 ng/ml.

++: DHBV DNA 1-10 ng/ml.

+++: DHBV DNA 10-100 ng/ml.

++++: DHBV DNA >100 ng/ml.

Date of Inoculation: 8-27-91 Sample: Test One, Day Two

Dilution of DHBV Inoculum	Duck Number	Slot Blot of Sera				Slot Blot of Liver DNA
		Week 0	1	2	3	
10^{-1}	P161	-	-	-	-	-
	P130	-	-	-	-	-
10^{-2}	P111	-	-	-	-	-
	P142					-
	P166	-	-	-	-	-
10^{-3}	P126§	-	-	-	-	NA
	P149§	-	-	-	-	NA
	P137§	-	-	-	-	NA
10^{-4}	P143§	-	-	-	-	NA
	P174*	++++	++	++	++	NA
	P146§	-	-	-	-	NA
10^{-5}	P141§	-	-	-	-	NA
	P147§	-	-	-	-	NA
	P134§	-	-	-	-	NA
10^{-6}	P170§	-	-	-	-	NA
	P165*	++++	+++	+++	++++	NA
	P151*	+	-	++++	-	NA
10^{-7}	P163	-	-	-	-	NA
	P140	-	-	-	-	NA
	P156	-	-	-	-	NA
10^{-8}	P173	-	-	-	-	NA
	P154	-	-	-	-	NA
	P164	-	-	-	-	NA

*DHBV positive when hatched (before inoculation of DHBV).

§Duck was raised in same cage with congenitally DHBV-positive duck (*).

NA: Not assayed.

+: DHBV DNA <1 ng/ml.

++: DHBV DNA 1-10 ng/ml.

+++: DHBV DNA 10-100 ng/ml.

++++: DHBV DNA >100 ng/ml.

SECTION IV

OPERATING PARAMETERS

Operating Parameters

A. Operating parameters are documented for each day of testing on specific log sheets. There are two (2) types of log sheets. The first log contains the following information:

1. Unit name
2. Unit Number
3. Unit location
4. Test date
5. Test start/complete time
6. Test manager/unit operator
7. Microwave Section (MWS) Screw Speed
8. Temperature Holding Section (THS) Screw Speed
9. Steam consumption
10. Shredder hour start/end time
11. Specimen #
12. Input time
13. Ejection time
14. Travel time (minutes)
15. Test organism
16. Test results (refer to laboratory report for results)
17. Remarks(lost vials, vials not retrieved, vials crushed, small volume).

B. The second log sheet contains the following information:

1. Time
2. Steam Temperature (Centigrade)
3. MWS Inlet Temperature (Centigrade)
4. MWS Exit Temperature (Centigrade)
5. THS Outlet Temperature (Centigrade)

Log sheets are in chronological order.

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HGA-250-S
UNIT NUMBER: 21927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 1, 1991
TEST START: 12:50 P.M.
TEST COMPLETE: 2:20 P.M.
TEST MANAGER: KIRK HARLAN
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: .9 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9 GP/H
SHREDDER HOURS START: 95.9
SHREDDER HOURS - END: 97.0

T = 0 = 12:50 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	12:50	1:43	:53	Nocardia		
2	12:51	1:45	:54			X
3	12:52	1:40	:48			
4	12:53	1:40	:47			X
5	12:54	-	-			XX
6	12:55	1:46	:51	B. subtilis		
7	12:55	1:46	:51			
8	12:55	1:58	1:03			X
9	12:55	1:56	1:01			
10	12:55	1:57	1:02			X
11	1:00	1:57	:57	Aspergillus		X
12	1:00	1:58	:58			
13	1:00	1:59	:59			
14	1:00	1:57	:57			
15	1:00	1:58	:58			X
16	1:05	2:01	:56	C. albicans		X
17	1:05	2:01	:56			
18	1:05	2:02	:57			X
19	1:05	2:03	:58			
20	1:05	2:02	:57			X
21	1:10	2:03	:53	Enterococcus		X
22	1:10	2:09	:59			
23	1:10	2:04	:54			
24	1:10	-	-			XX
25	1:10	2:05	:55			

KEY MARKS: X = VIAL EMPTY XX = VIAL NOT RECOVERED

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
26	1:15	2:06	:51	Staph. aureus		
27	1:15	2:06	:51			
28	1:15	-	-			XX
29	1:15	2:06	:51			
30	1:15	2:17	1:02			X
31	1:20	2:10	:50	Ps. aeruginosa		
32	1:20	2:12	:52			X
33	1:20	2:12	:52			
34	1:20	2:10	:50			X
35	1:20	2:10	:50			
36						
37						
38						
39						
40						
41						
42						
43						
44						
45						
46						
47						
48						
49						
50						

REMARKS: X = VIAL FMITY XX = VIAL NOT RECOVERED

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 3, 1991
TEST START: 1:35 P.M.
TEST COMPLETE: 3:03 P.M.

T = 0 = 1:35 P.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	162	97	97	100	
5	161	97	97	99	
10	159	94	96	97	
15	162	94	95	98	
20	161	96	95	96	
25	159	97	95	96	
30	160	98	94*	95	system. fail - *
35	162	97	94*	99	system. fail - *
40	156	97	96	96	
45	160	98	94*	95	system. fail - *
50	162	98	97	99	
55	160	98	96	97	
60	162	97	96	96	
65	161	98	97	98	
70	160	97	96	99	auto-stop T = 1:07
75	162	97	97	97	MWG-1-Out
80	160	96	96	97	MWG-1-2-3-4-out
85	160	95	94	96	MWG 5-6 out
90	162	95	94*	95	system. fail - *
95					
100					
105					
110					
115					
120					

REMARKS: System failure - * = Temperature parameters not met

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 10, 1991
TEST START: 12:30 P.M.
TEST COMPLETE: 2:28 P.M.
TEST MANAGER: WALTER DILLMAN
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9.0 GP/H
SHREDDER HOURS START: 112.40
SHREDDER HOURS - END: 113.40

T = 0 = 12:30 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	12:30	1:24	:54	B. subtilis*		
2	12:30:30	1:24	:54:30			
3	12:31	1:26	:57			
4	12:31:30	1:26	:57:30			
5	12:32	1:27	:55			
6	12:33	1:27	:54			
7	12:33:30	1:29	:55:30			
8	12:34	1:29	:55			
9	12:34:30	1:28	:53:30			
10	12:35	1:28	:53			
11	12:35:30	1:31	:55:30	Myco. bovis		
12	12:36	1:36	1:00			
13	12:36:30	1:31	:54:30			
14	12:37	1:32	:55			
15	12:37:30	1:30	:52:30			
16	12:38	1:34	:56	Myco. fortuitum		
17	12:38:30	1:29	:50:30			
18	12:39	1:29	:50			
19	12:39:30	1:30	:50:30			
20	12:40	1:30	:50			
21						
22						
23						
24						
25						

REMARKS: Contamination noted during unload

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT JIG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: JIG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 10, 1991
TEST START: 12:30 P.M.
TEST COMPLETE: 2:28 P.M.

T = 0 = 12:30 P.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	160	98	97	100	
5	159	98	98	100	
10	162	98	97	100	
15	162	98	97	100	
20	160	98	97	100	
25	162	98	97	100	
30	162	98	97	100	
35	160	98	97	100	
40	161	98	97	100	
45	159	98	97	100	
50	160	98	97	100	
55	159	97	97	100	
60	161	98	97	100	
65	162	98	97	100	
70	161	97	97	100	
75					
80					
85					
90					
95					
100					
105					
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927 01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 11, 1991
TEST START: 1:15 P.M.
TEST COMPLETE: 2:34 P.M.
TEST MANAGER: WALTER DILLMAN
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9.0 GPH
SHREDDER HOURS START: 114.55
SHREDDER HOURS - END: 115.58

T = 0 = 1:15 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	1:15	2:26	1:11	B. subtilis*		
2	1:15:30	2:26	1:10:30			
3	1:16	2:26	1:10			
4	1:16:30	2:26	1:09:30			
5	1:17	2:28	1:11			
6	1:17:30	2:30	1:12:30			
7	1:18	2:27	1:09			
8	1:18:30	2:27	1:08:30			
9	1:19	2:21	1:02			
10	1:19:30	2:27	1:07:30			
11	1:20	2:34	1:14	Myco. bovis		
12	1:21	2:34	1:13			
13	1:22	2:29	1:07			
14	1:23	2:30	1:07			
15	1:23:30	2:30	1:06:30			
16	1:25	2:29	1:04	Myco. fortuitum		
17	1:25:30	2:29	1:03:50			
18	1:26	2:29	1:03			
19	1:26:30	2:30	1:03:30			
20	1:27	2:30	1:03			
21	1:27:30	2:28	1:00:30	Duck HBV		
22	1:28	2:28	1:00			
23						
24						
25						

REMARKS: *Company approved organism

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 11, 1991
TEST START: 1:15 P.M.
TEST COMPLETE: 2:34 P.M.

T = 0 = 1:15 P.M.

TIME (MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	161	98	97	98	
5	161	97	96	99	
10	159	97	97	98	
15	161	97	96	98	
20	161	97	97	97	
25	161	98	97	100	
30	162	98	97	100	
35	159	97	97	100	
40	161	97	98	100	
45	160	98	98	100	
50	162	98	97	100	
55	160	98	97	100	
60	160	97	97	100	
65	161	98	97	100	
70	160	98	97	100	
75	161	97	97	100	
80	160	98	97	100	
85	160	98	97	100	
90					
95					
100					
105					
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 16, 1991
TEST START: 11:55 P.M.
TEST COMPLETE: 1:35 P.M.
TEST MANAGER: WALTER DILLMAN
UNIT OPERATOR: BILL MOORES

MVS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9.0 GPH
SHREDDER HOURS START: 118.47
SHREDDER HOURS - END: 119.97

T = 0 = 11:55 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	11:55	1:21	1:26	Enterococcus		
2	11:55	1:21	1:26			
3	11:56	1:22	1:26			X
4	11:56	1:23	1:27			
5	11:57	1:21	1:24			
6	11:57	1:21	1:24	Ps. aeruginosa		
7	11:58	1:21	1:23			
8	11:58	1:21	1:23			
9	11:59	1:25	1:26			
10	11:59	1:24	1:25			
11	12:00	1:22	1:22	Staph. aureus		
12	12:00	1:25	1:25			
13	12:01	1:23	1:22			
14	12:01	1:23	1:22			
15	12:02	1:24	1:22			
16	12:02	1:27	1:25	Myco. bovis		
17	12:03	1:24	1:21			
18	12:03	1:24	1:21			
19	12:04	1:24	1:20			
20	12:04	1:24	1:20			
21	12:05	1:24	1:19	Myco. fortuitum		
22	12:05	1:35	1:30			
23	12:06	1:26	1:20			
24	12:06	1:27	1:21			
25	12:07	1:26	1:19			

REMARKS: X=EMPTY VIAL

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
26	12:07	1:26	1:19	B. subtilis*		
27	12:08	1:27	1:19			
28	12:08	1:30	1:22			
29	12:09	1:26	1:17			
30	12:09	1:27	1:18			
31	12:10	1:27	1:17			
32	12:10	1:27	1:17			
33	12:11	1:30	1:19			
34	12:11	1:28	1:17			
35	12:12	1:31	1:19			
36	12:12	1:29	1:17	C. albicans		
37	12:13	1:29	1:16			
38	12:13	1:29	1:16			
39	12:14	1:31	1:17			
40	12:14	1:29	1:15			
41	12:15	1:29	1:14	Nocardia		
42	12:15	1:30	1:15			
43	12:16	1:30	1:14			
44	12:16	1:34	1:18			
45	12:17	1:30	1:13			
46	12:17	1:31	1:14	Aspergillus		
47	12:18	1:31	1:13			
48	12:18	1:31	1:13			
49	12:19	1:31	1:12			
50	12:19	1:31	1:12			

REMARKS: * - Connecticut protocol organism

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
51	12:20	1:31	1:11	B. subtilis		
52	12:20	1:35	1:15			
53	12:21	1:31	1:10			
54	12:21	1:32	1:11			
55	12:22	1:32	1:10			
56	12:23	1:32	1:09	Duck HBV		

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: JULY 16, 1991
TEST START: 11:55 A.M.
TEST COMPLETE: 1:35 P.M.

T = 0 = 11:55 A.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	160	98	97	100	
5	159	98	97	100	
10	161	98	97	101	
15	162	98	97	101	
20	161	98	97	100	
25	161	98	97	100	
30	161	98	97	100	
35	161	97	96	100	
40	162	98	97	99	
45	159	98	97	101	
50	162	98	97	100	
55	161	98	97	101	
60	161	98	97	101	
65	161	98	97	100	
70	158	98	97	101	
75	159	98	97	100	
80	160	98	97	100	
85	159	98	97	101	
90	161	98	97	101	
95	162	98	97	100	
100	160	98	97	100	
105	162	98	97	100	
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 8, 1991
TEST START: 11:23 A..M.
TEST COMPLETE: 12:33 P.M.
TEST MANAGER: WALTER DILLMAN
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 8.2 RPM
STEAM CONSUMPTION: 8.0 GPM
SHREDDER HOURS START: 149.08
SHREDDER HOURS - END: 150.10

T = 0 = 11:23 A.M.

SPECIMEN #	INPUT TIME(MIN.)	EJECTION TIME(MIN.)	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	11:23	12:27	1:04	Giardia		
2	11:23.30	12:27	1:03.30			
3	11:24	12:32	1:08			
4	11:24.30	12:29	1:04.30			
5	11:25.	12:31	1:06			
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REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 8, 1991
TEST START: 11:23 A.M.
TEST COMPLETE: 12:33 P.M.

T = 0 = 11:23 A.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	TIS OUTLET TEMP. (C)	NOTES
0	160	98	97	99	
5	161	98	97	100	
10	159	98	97	100	
15	161	98	97	100	
20	161	98	97	100	
25	161	98	97	101	
30	161	98	97	101	
35	161	98	97	100	
40	161	98	97	100	
45	161	98	97	100	
50	161	98	97	101	
55	161	98	97	101	
60	161	98	97	101	
65	161	98	97	100	
70	161	98	97	100	
75					
80					
85					
90					
95					
100					
105					
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HC-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HC-A-250-S
UNIT NUMBER: 27937-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 9, 1991
TEST START: 11:26 A.M.
TEST COMPLETE: 12:42 P.M.
TEST MANAGER: WALTER DILLMAN
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 8.0 RPM
STEAM CONSUMPTION: 8.0 GPM
SHREDDER HOURS START: 152.90
SHREDDER HOURS - END: 154.00

T = 0 = 11:26 A.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	11:26	12:42	1:16	Giardia		small vol
2	11:26:30	12:40	1:13:30			small vol
3	11:27	12:39	1:12			
4	11:27:30	12:40	1:12:30			X
5	11:28	12:38	1:10			
6						
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(X MARKS X = EMPTY VIAL)

ADB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 9, 1991
TEST START: 11:26 A.M.
TEST COMPLETE: 12:42 P.M.

T = 0 = 11:26 A.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	160	98	97	100	
5	161	98	97	101	
10	161	98	97	101	
15	160	98	97	100	
20	160	98	97	101	
25	160	98	97	100	
30	161	98	97	101	
35	161	98	97	100	
40	160	98	97	100	
45	159	98	97	100	
50	160	98	96	100	
55	160	98	97	100	
60	161	98	96	100	
65	160	98	97	101	
70	161	98	96	100	
75	161	98	97	100	
80	161	98	97	100	
85					
90					
95					
100					
105					
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 12, 1991
TEST START: 11:30 A.M.
TEST COMPLETE: 12:41 P.M.
TEST MANAGER: BILL MOORES
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 8.0 RPM
STEAM CONSUMPTION: 8.0 GPH
SHREDDER HOURS START: 155.80
SHREDDER HOURS - END: 156.90

T = 0 = 11:30 A.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	11:30	12:41	1:11	Giardia		
2	11:30	12:41	1:11			
3	11:31	12:40	1:09			
4	11:31	12:39	1:08			
5	11:32	12:39	1:07			
6	11:32	12:39	1:07			
7	11:33	12:40	1:07			
8	11:33	12:40	1:07			
9	11:34	12:41	1:07			
10	11:34	12:41	1:07			
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REMARKS: ALL SAMPLES RETRIEVED

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A 250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: AUGUST 12, 1991
TEST START: 11:30 A.M.
TEST COMPLETE: 12:41 P.M.

T = 0 = 11: 23 A.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	161	97	97	100	
5	160	97	97	100	
10	160	98	97	100	
15	161	97	97	100	
20	160	98	97	100	
25	161	98	97	100	
30	160	98	97	100	
35	161	98	96	100	
40	161	98	96	100	
45	160	98	97	100	
50	160	98	97	101	
55	160	98	96	100	
60	161	98	96	100	
65	160	98	96	100	
70	160	98	97	101	
75					
80					
85					
90					
95					
100					
105					
110					
115					
120					

REMARKS:

SECTION V

ADDITIONAL DATA

NORTH AMERICAN LABORATORY GROUP

1 Lake Street
New Britain, CT
06052
203-826-1140

October 8, 1991

TO: Ed Krisiunas
Safeway Disposal Systems, Inc.

FROM: Dr. Richard C. Tilton
North American Laboratory Group

REF: Giardia miura tests on ABB microwave device

1. A vial of 1 x 10^7 cysts/ml. of Giardia miura were received on October 4, 1991 from Cleveland State University (CSU). Following were processed at Safeway as follows: Initial cysts concentration was provided by CSU.

   a. 2 controls - transported to Safeway and returned back to lab. 4 tests - transported to Safeway, processed, returned to lab. Date/time of return - 1730, October 4, 1991.

   b. Controls (1 + 2) and test vials (3-6) contained approximately 0.5 ml. of Giardia cyst suspension diluted 1:10 for a final count of 1 x 10^6 ml.

   c. Controls and test vials (1 x 10^6) were examined microscopically (55x, high dry) showed 3-10 cysts per field.

2. Excystment

   a. Excystment was carried out according to the method of Rice and Schaeffer (JCM 14, 709-710. 1981) using reagents (except HCL and $NaHCO_3$) provided by Cleveland State University.

B. All control and test vials were examined microscopically following the excystment procedure, using an oil immersion lens (100x). Both cysts and trophs were counted. Average #'s of Giardia cysts and trophs per oil field was 2-3 p/oif on controls and 1-2 p/oif on the test vials.

C. Controls showed approximately 70% excystment. In the average field, 2 of 3 Giardia were trophs.

No trophs were observed in the test vials (3-6) (excystment = 0%). Reduction in organism count on the test vials could well have been due to cyst rupture during the microwave process. An excystment protocol was performed on a portion of the cysts prior to shipping from Cleveland. Excystment efficiency was 80%.

D. Approximately 150-200 cysts/trophs per specimen were counted.

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: OCTOBER 4, 1991
TEST START: 1:00 P.M.
TEST COMPLETE: 2:02 P.M.
TEST MANAGER: ED KRISIUNAS
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9.0 GP/H
SHREDDER HOURS START: 179.02
SHREDDER HOURS - END: 180.10

T = 0 = 1:00 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	1:00	1:59	59	Giardia muris		
2	1:00.30	2:02	1:01.30	"		
3						
4						
5						
6						
7						
8						
9						
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11						
12						
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REMARKS: ALL SAMPLES RECOVERED

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFEWAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: OCTOBER 4, 1991
TEST START: 1:00 P.M.
TEST COMPLETE: 2:02 P.M.

T = 0 = 1:00 P.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	160	96	97	99	
5	157	96	97	99	
10	157	96	97	99	
15	157	96	96	98	
20	160	98	97	99	
25	159	98	97	99	
30	160	98	97	100	
35	160	99	98	100	
40	160	99	98	100	
45	160	99	98	100	
50	159	98	97	99	
55	160	99	98	99	
60	160	99	98	99	
65	160	99	98	99	
70					
75					
80					
85					
90					
95					
100					
105					
110					
115					
120					

REMARKS:

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: OCTOBER 4, 1991
TEST START: 3:30 P.M.
TEST COMPLETE: 4:40 P.M.
TEST MANAGER: ED KRISIUNAS
UNIT OPERATOR: BILL MOORES

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: 7.2 RPM
STEAM CONSUMPTION: 9.0 GP/H
SHREDDER HOURS START: 193.4
SHREDDER HOURS - END: 194.0

T = 0 = 3:30 P.M.

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	3:30	4:20	50	Giardia muris		
2	3:30.5	4:36	1:05.5	"		
3						
4						
5						
6						
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10						
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REMARKS: ALL SAMPLES RECOVERED

ABB SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A-250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A-250-S
UNIT NUMBER: 27927-01
UNIT LOCATION: SAFE WAY DISPOSAL, MIDDLETOWN, CT

TEST DATE: OCTOBER 4, 1991
TEST START: 3:30 P.M.
TEST COMPLETE: 4:40 P.M.

T = 0 = 3:30 P.M.

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	155	98	99	99	
5	155	98	97	99	
10	155	98	97	97	
15	157	98	97	99	
20	157	98	97	99	
25	160	99	97	99	
30	160	98	97	99	
35	160	99	98	99	
40	160	98	98	99	
45	160	99	98	99	
50	160	98	98	99	
55	160	98	98	99	
60	160	99	98	99	
65	160	99	98	99	
70					
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REMARKS:

SECTION VI

SUMMARY

SUMMARY

The high level of disinfection/sterilization from this data clearly demonstrates the ABB Sanitec Microwave Disinfection System is capable of meeting the parameters set for alternative technologies to treat and destroy biomedical waste as established by the state of New York.

ATTACHMENT III.

MICROWAVE DISINFECTION SYSTEM

MODEL HG-A-250
MODEL HG-A-100

MICROBIOLOGICAL EFFICACY STUDY

FOR THE

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

TABLE OF CONTENTS		
I	SUMMARY	P. 1
II	EFFICACY PROTOCOL	P. 2
	RESULTS	P. 6
	CONCLUSION	P. 7
III	DATA	P. 8
IV	OPERATING PARAMETERS	P. 16
	250 UNIT	
	100 UNIT	
V	APPENDIX	

SECTION I

SUMMARY

Sanitec Microwave Disinfection System
IEPA Efficacy Protocol

I. Introduction - Process Description

The Sanitec Microwave Disinfection Units are designed to shred and disinfect biomedical waste. When operated in accordance with all of Sanitec's written procedures and instructions, the systems will render biomedical waste disinfected, unrecognizable, and of no greater risk to the public health than normally associated with residential household waste. Model HG-A 250S is rated to process 250 kg./hour. Model HG-A 100S is rated to process 100 kg./hour.

The disinfection process is computer controlled. The unit has a hydraulic lift mechanism to hoist and dump waste containers into a hopper on top of the unit. The hopper has a sealed lid that opens and closes automatically. Inside the hopper, the bags and boxes of waste are directed towards a shredding device by a feed arm. The feed arm assists in forcing material into the shredder. Sensors monitor the amount of material moving into the hopper. Shredded material falls onto an auger-driven conveyor. As the waste enters the auger-driven conveyor, 150°C (300°F) steam is injected and conveyed through the microwave conveyor section. A series of microwave generators input energy to maintain uniform heating of the waste at a minimum temperature of 95°C (203°F). The action of the auger also provides additional mixing to ensure uniform heating. In the 250 kg./hr. unit, the waste is then transported to a holding section. The output waste then enters an upward inclined discharge tube which is unheated. The final temperature and time profile is a minimum of 95°C (203°F) for 30 minutes. The cooling waste may be processed through a secondary shredder to completely destroy any partially recognizable waste still remaining after the initial shredding and treatment process. The final waste product then falls into a dumpster or similar waste transport container that may be used to transport the disinfected waste to a repository.

II. Purpose

The purpose of the tests described in this report was to demonstrate the effectiveness of the ABB Sanitec microwave disinfection process in accordance with 35 Ill. Adm. Code 1422 - Initial Efficacy Test. Tests were conducted on two Sanitec Microwave Disinfection Systems - the HG-A 250S and HG-A 100S.

Two types of indicators were used: spore strips containing *Bacillus subtilis* ATCC strain 19659, enclosed in glassine envelopes; and spore strips containing *Bacillus subtilis* ATCC strain 9372, enclosed in polypropylene vials. The number of samples tested was exceeded that required to provide a greater margin of evidence. The vials are a commercially available, very simple means of performing frequent testing, as the operator of the microwave unit can introduce the vials, retrieve them, and incubate them on-site without requiring the time and expense of laboratory culturing. The vials show either a presence or absence of spores, and because each strip contains a minimum of 1×10^6 spores, such an absence demonstrates that the microwave unit at least meets the State's requirements of a 6-log spore kill (See Appendix).

The purpose of concurrent testing of the two types of samples was to compare the two strains of *B. subtilis* and determine any difference in efficacy demonstration, so as to determine feasibility of using the ATTEST vials containing the ATCC *B. subtilis* spore strain 9372 during monthly periodic verification tests.

III. Microbiological Testing

The Initial Efficacy Test was conducted using Option 3 of Appendix A, as the microwave systems are treatment units that use thermal treatment and maintain the integrity of the container of indicator microorganism spores.

In accordance with 35 Ill. Adm. Code 1422, samples of *Bacillus subtilis* (ATCC 19659) were introduced in the units with each of three challenge loads. At the same time, in the same carrier sack, samples of *Bacillus subtilis* (ATCC 9372) were introduced. The three types of challenge loads comprised normal medical waste and included at a minimum, 5% of each of the following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers and bottles of liquids. Composition was verified by pre-testing segregation of waste, visual inspection, and weighing.

Challenge Loads

The Sanitec Microwave units are continuous processing systems. Thus, the Illinois Environmental Protection Agency (IEPA) has determined that a "challenge load" is equal to one cartful, or hopper load, of waste. Typically, each cartload of waste weighs approximately 100 pounds.

Bags of waste were placed into a cart and weighed. For Challenge Loads A and B, the appropriate amount of moisture was added in the form of water contained in 2-liter plastic bottles, glass bottles, or unused plastic sharps containers.

Composition of Challenge Loads Percent by Weight			
Moisture	A ≤5	B ≥50	C —
Organic	—	—	≥70

IV. Sample Preparation

Samples in glassine envelopes were prepared at North American Laboratory Group (NALG), New Britain, Connecticut. Spores of *B. subtilis* strain 19659 were grown in a nutrient broth at 35°C for 48 hrs. Vegetative cells were centrifuged, resuspended in a non-nutrient medium, and refrigerated at 4°C for 48 hours to induce sporulation. Extent of sporulation was >99%. The spore suspension was adjusted to $1x10^7$ cfu/ml and 60 microliters of suspension was added to cellulose strips. Because of elution inconsistencies and sampling variation, the range of spore concentration was from $5x10^5$ to $3x10^6$. The spore strips were placed in glassine envelopes.

Spore strips contained in the ATTEST vials had a mean population per strip of 2.3×10^6.

V. Test Procedure

1. Samples made at NALG were transported to the test site. ATTEST samples had been previously obtained. Samples were at room temperature.

2. In accordance with the manufacturer's instruction, the units conformed to the following specifications:

   - the average temperature of the infed waste was not less than 0°C (32°F)
   - the Microwave Section inlet temperature was not less than 95°C (203°F). The Temperature Holding Section exit temperature was not less than 95°C (203°F).

   To ensure proper conditions for disinfection, the unit control system is designed to monitor and control the exit temperature by means of speed control on the conveyor to allow residence time (30 minutes) for the waste to reach the treatment temperature. The unit is equipped with a strip chart record such that proper monitoring of operating conditions and record are maintained by recording the Microwave Section inlet temperature and the speed (rpm) of the microwave screw conveyor.

3. Each test with each of the Challenge Loads A, B, and C consisted of a total of ten (10) biological indicators. Each indicator was placed into a brightly colored cloth sack that was numbered for easy retrieval. Five (5) of the microbiological samples were the spore strips prepared by NALG (*B. subtilis* ATCC 19659). The remaining five (5) samples were ATTEST biological indicators (ATCC 9372).

   The purpose of concurrent testing of the two types samples was to determine feasibility of using the ATTEST vials containing the ATCC *B. subtilis* spore strain 9372, to determine efficacy of the microwave units during the monthly verification testing.

4. Samples were inserted approximately every 3 minutes through a cylindrical port located at the transfer hopper. The port is positioned after the shredder but prior to treatment, so the integrity of carrier vials is maintained.

5. In addition to the test samples, four (4) untreated controls for each test (two (2) of each type) were processed in the same manner as the test samples, with the exception of not being introduced into the microwave units. These untreated active control samples served to ensure that the indicators were not inadvertently killed by some other step in the processing.

6. During the test procedure, the following data were recorded:

   - date
   - name of responsible test manager
   - biological indicator
   - insertion time of each sample into unit
   - discharge time of each sample from unit
   - temperatures of the following, recorded at 5-minute intervals:
     - Microwave Section inlet
     - Microwave Section exit
     - Temperature Holding Section exit
     - Steam
   - additional remarks, observations, or comments

7. Test samples traversed the full cycle of the microwave disinfection process. The samples were allowed to drop freely from the unit discharge into a dumpster along with other treated PIMW. Residence times were calculated and recorded for each individual sample.

VI. Sample Testing

1. The spore strips contained in glassine envelopes (test samples and controls) were returned to NALG in the glassine envelopes. The strips were removed from the glassine envelopes with sterile tweezers under aseptic conditions. All strips were placed in tubes with 10 ml. of trypticase soy broth, and incubated at room temperature for 30 minutes. The tubes were then vortexed to disrupt and remove the spores from the strip. Multiple aliquots (three) of the broth were quantitatively cultured on Nutrient agar plates. The plates were incubated at 37°C for 48 hours. Colonies were counted. Gram stains were performed on any colony that did not resemble *B. subtilis* morphologically (approx. 15).

2. The 3M ATTEST vials were placed into a dry block (37° +/- 1°C) at the test site. The block used, ATTEST Biological Incubator Model No. 127 (3M), is designed to break the inner glass ampule as the plastic container is pushed into the heating block. The indicators were examined twice daily for color change. The appearance of a yellow color indicates bacterial growth. No color change indicates destruction of the spores.

VII. Results

Control strip colonies were recorded for both the HG-A 250s and HG-A 100S microwave units. The data reflect the range of colony counts determined on repetitive samples of the 10 ml. tube containing the *B. subtilis* spore strips.

The preparation of *B. subtilis* spore strips is not a precise quantitative procedure. While the target concentration is $1x10^6$ cfu/ml, there is an expected variation around this target concentration due to a number of factors, the most important of which is anticipated sampling error when bacterial colony counts are performed.

With the exception of one sample, all test samples revealed no viable spores. Controls were within the target range of $1x10^6$ cfu/ml, allowing for inherent variation in bacterial colony counts. With the exception of one specimen, all specimens showed an average 6-log kill, while the one exception showed an approximate 5 log kill.

All of the ATTEST samples displayed complete destruction of spores, which indicates at least a 6-log kill of bacterial spores.

VIII. CONCLUSION

The initial efficacy tests indicate that under the prescribed operating conditions, there was a 6-log kill of *Bacillus subtilis* spores enclosed in both types of carrier. Therefore, the Sanitec HG-A 250S and HG-A 100S Microwave Disinfection Systems are capable of meeting the parameters set for potentially infectious medical waste treatment systems as established by the State of Illinois.

There is no difference between challenge testing of the microwave using *Bacillus subtilis* ATCC strain 9372, contained in polypropylene vials; and *Bacillus subtilis* ATCC strain 19659, contained in glassine envelopes. It is acceptable to conduct future periodic verification tests using either mechanism.

Signed: Richard C. Tilton, Ph.D.
Name
Sr. Vice President and Chief Scientific Officer
Title
North American Laboratory Group, Inc.
Independent Certified Laboratory

SECTION III

DATA

DATA

DATE: *July 20, 1993*

SITE: *SafeWay Disposal Systems, Middletown, CT*

Test loads comprised biomedical waste from various sources. For several days prior to testing, waste was segregated to reflect the compositions as required by IEPA. Examples of waste processed during testing include: sharps containers; plastics (tubes, vials, bags); IV bags; glass; gloves; gowns; booties and masks (non-woven fibers); bedding (woven fibers); and gauze. Organic material comprised blood, tissue samples, tissue cultures, and specimens.

Each of the three (3) challenge loads was tested using five (5) spore strips and five (5) ATTEST vials. Two (2) NALG-prepared spore strip and two (2) ATTEST controls were assigned to each test load. For each unit model:

- samples 1-5 and controls A and B pertain to Challenge Load A
- samples 6-10 and controls C and D pertain to Challenge Load B
- samples 11-15 and controls E and F pertain to Challenge Load C

Not all of the ATTEST samples were incubated. The dry block holds only 28 vials, so 11 test vials and three (3) controls, one for each load, were incubated for each test load.

SANITEC MICROWAVE DISINFECTION SYSTEM

MODEL HG-A 250S

CHALLENGE LOAD A - ≤5% Moisture	
Samples 1-5	Controls A and B
Weight of Load	121.6 lbs.
Weight of Water	9.0 lbs. (7.40%)

CHALLENGE LOAD B - ≥50% Moisture	
Samples 6-10	Controls C and D
Weight of Load	105.8 lbs.
Weight of Water	54.0 lbs. (51.03%)

CHALLENGE LOAD C - ≥70% Organic	
Samples 11-15	Controls E and F
Weight of Load	116 lbs.
Weight of Water	90 lbs. organic (77.59%)

SANITEC MICROWAVE DISINFECTION SYSTEM

MODEL HG-A 100S

CHALLENGE LOAD A - ≤5% Moisture	
Samples 1-5	Controls A and B
Weight of Load	102 lbs.
Weight of Water	13 lbs. (12.75%)

CHALLENGE LOAD B - ≥50% Moisture	
Samples 6-10	Controls C and D
Weight of Load	102.6 lbs.
Weight of Water	53.4 lbs. (52.05%)

CHALLENGE LOAD C - ≥70% Organic	
Samples 11-15	Controls E and F
Weight of Load	121 lbs.
Weight of Water	95 lbs. organic (78.51%)

NALG - PREPARED SAMPLES - CONTROLS

MODEL HG-A 250S

Strip designation	Range of colony counts (cfu/ml)
CA	$5x10^5$ - $1.5x10^6$
CB	$6.5x10^5$ - $3X10^6$
CC	$5x10^5$ - $1x10^6$
CC	$6x10^5$ - $2x10^6$
CD	$5x10^5$ - $1.5x10^6$
CE	$5x10^5$ - $1.0x10^6$

MODEL HG-A 100S**

Strip designation	Range of colony counts (cfu/ml)
CA	$5x10^5$ - $1.5x10^6$
CC	$6x10^5$ - $2x10^6$
CE	$6.5x10^5$ - $1x10^6$

** For consistency, not all were cultured.

MODEL HG-A 250S

Sample	Result
1 (Challenge Load A)	No Growth
2	"
3	"
4	"
5	"
Controls	Growth
6 (Challenge Load B)	No Growth
7	"
8	"
9	"
10	"
Controls	Growth
11 (Challenge Load C)	50 cfu/ml
12	No Growth
13	"
14	"
15	"
Controls	Growth

MODEL HG-A 100S

Sample	Result
1 (Challenge Load A)	No Growth
2	"
3	"
4	"
5	"
Control	Growth
6 (Challenge Load B)	No Growth
7	"
8	"
9	"
10	"
Control	Growth
11	No Growth
12	"
13	"
14	"
15	"
Control	Growth

RESULTS AND CONCLUSION

With the exception of specimen HG-A 250S (11), all test samples revealed no viable spores. Controls were within the target range of $1x10^6$ cfu/ml, allowing for inherent variation in bacterial colony counts. With the exception of specimen HG-A 250S (11), all specimens showed an average 6-log kill, while specimen HG-A 250S (11) showed an approximate 5-log kill.

All ATTEST samples showed complete destruction of all spores, indicating at least a 6-log kill of spores.

The initial efficacy tests indicate that under the prescribed operating conditions, there was a 6-log kill of *Bacillus subtilis* spores enclosed in both types of carrier. Therefore, the Sanitec HG-A 250S and HG-A 100S Microwave Disinfection Systems are capable of meeting the parameters set for PIMW treatment systems as established by the State of Illinois.

There is no difference between challenge testing of the microwave using *Bacillus subtilis* ATCC strain 9372, contained in polypropylene vials; and *Bacillus subtilis* ATCC strain 19659, contained in glassine envelopes. It is acceptable to conduct future periodic verification tests using either mechanism.

ATTEST SAMPLES - INCUBATION DATA

The ATTEST heat block incubator holds 28 samples, so only 11 test samples (one group of 3 and two groups of 4) and 3 controls (one from each challenge load) were incubated.

MODEL HG-A 250S

Samples incubated:	Result
1 (Challenge Load A) 2 3	No Growth " "
Control A	Growth
6 (Challenge Load B) 7 8 9	No Growth " " "
Control C	Growth
11 (Challenge Load C) 12 13 14	No Growth " " "
Control E	Growth

MODEL HG-A 100S

Samples incubated:	Result
3 (Challenge Load A) 4 5	No Growth " "
Control A	Growth
7 (Challenge Load B) 8 9 10	No Growth " " "
Control C	Growth
12 13 14 15	No Growth
Control E	Growth

ATTEST MICROBIOLOGICAL INDICATORS

These indicators are manufactured by 3M Corporation. The product consists of a dry spore strips containing *B. subtilis* var. niger ATCC 9372, with a mean population/strip of 5.1×10^6 cfus. Growth medium is continued in a crushable ampule. The medium is a modified Tryptic Soy broth with a pH-sensitive indicator dye (bromomythl blue). A flexible polypropylene vial holds the dry spore strip and the medium ampule. A green polypropylene cap with a hole, covered by a hydrophobic filter (tyvek) covers the vial. When incubated in a heat block, the chemical indicator changes color in the presence of bacteria.

SECTION IV

OPERATING PARAMETERS

OPERATING PARAMETERS

Operating parameters were documented on log sheets used during regular tests of the Sanitec Microwave Units. Data are recorded as deemed necessary by the test manager.

The first log sheet contains the following information:

1. *Unit name and number (if applicable)*
2. *Unit location*
3. *Test date*
4. *Test start/complete time*
5. *Test manager/unit operator*
6. *Microwave and temperature holding sections screw speeds*
7. *Steam consumption*
8. *Shredder hour start/end time*
9. *Specimen number*
10. *Input time*
11. *Ejection time*
12. *Travel time (in minutes)*
13. *Test organism*
14. *Test results (refer to laboratory report for results)*
15. *Remarks (samples or vials not retrieved, vials crushed, etc.)*

The second log sheets contains the following information:

1. *Time*
2. *Steam Temperature*
3. *MWS Inlet Temperature*
4. *MWS Exit Temperature*
5. *THS Outlet Temperature*

SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A 250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A 250-S
UNIT NUMBER: ABBS-001
UNIT LOCATION: SAFEWAY, CT

TEST DATE: 7/20/93
TEST START: 11:35 am
TEST COMPLETE: 3:05 pm
TEST MANAGER: S. HELTON
UNIT OPERATOR: E. BIRGY

MWS SCREW SPEED: 1 RPM
THS SCREW SPEED: 8 RPM
STEAM CONSUMPTION: ____ GP/H
SHREDDER HOURS START: 5868
SHREDDER HOURS - END: 5872

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	11:38	2:05	147	B. SUBTILIS		
2	11:35	2:02	147	SPORES 19659		
3	11:41	2:05	144	and 9372		
4	11:44	2:16	152			
5	11:47	2:33	166			
6						
7	11:50	2:18	148			
8	11:53	2:26	153			
9	11:56	2:26	150			
10	11:59	2:55	176			
11	12:02	2:34	152			
12						
13	12:05	2:44	159			
14	12:08	2:46	158			
15	12:11	2:55	164			
16	12:14	2:45	151			
17	12:17	3:05	168			
18						
19						
20						
21						
22						
23						
24						
25						

REMARKS: Ca in 11:35 - out 2:03; MWG 1 and 2 off, 3,4,5 and 6 MWG enabled.

SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A 250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A 250-S
UNIT NUMBER: ABBS-001
UNIT LOCATION: SAFEWAY, CT

TEST DATE: 7/20/93
TEST START: 11:35am
TEST COMPLETE: 3:05 pm

T=0= 11:35

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	156	95	97	100	
5	157	95	97	99	
10	157	95	97	99	
15	155	95	97	99	
20	157	95	97	100	
25	157	95	97	100	
30	157	95	97	100	
35	155	95	97	100	
40	156	95	97	100	
45	157	95	97	100	
50	157	95	97	100	
55	156	95	97	100	
60	157	95	97	100	
65	157	95	97	100	
70	157	95	97	100	
75	156	95	97	100	
80	157	95	97	100	
85	157	95	97	100	
90	157	95	97	100	
95	157	95	97	100	
100	158	95	97	100	
105	158	95	97	100	
110	158	95	97	100	
115	158	95	97	100	
120	157	95	97	100	

REMARKS: MWG 1 and 2 off; 3,4,5 and 6 MWG enabled.

SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A 250-S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A 250-S
UNIT NUMBER: ABBS-001
UNIT LOCATION: SAFEWAY, CT

TEST DATE: 7/20/93
TEST START: 11:35 am
TEST COMPLETE: 3:05 pm

T = 0 =

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	155	95	97	100	
5	156	95	97	100	
10	156	95	97	100	
15	157	95	97	100	
20	156	95	97	100	
25	156	95	97	100	
30	156	95	97	100	
35	156	95	97	100	
40	156	95	97	100	
45	157	95	97	100	
50	156	95	97	100	
55	156	95	97	100	
60	157	95	97	100	
65	156	95	97	100	
70	156	95	97	100	
75	156	95	97	100	
80	157	95	97	100	
85	157	95	97	100	
90					
95					
100					
105					
110					
115					
120					

REMARKS:

SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A 100-S MICROBIOLOGICAL TEST

UNIT NAME: HG-A 100-S
UNIT NUMBER: #1
UNIT LOCATION: SAFEWAY-MIDDLETOWN, CT

TEST DATE: 7/20/93
TEST START: 2:20 pm
TEST COMPLETE: 4:35
TEST MANAGER: S. HELTON
UNIT OPERATOR: E. BIRGY

MWS SCREW SPEED: 1.0 RPM
THS SCREW SPEED: N/A RPM
STEAM CONSUMPTION: _____ GPM
SHREDDER HOURS START: _____
SHREDDER HOURS - END: _____

SPECIMEN #	INPUT TIME	EJECTION TIME	TRAVEL TIME(MIN.)	TEST ORGANISM	STERILE(Y/N)	REMARK
1	3:20	4:26	66	B. SUBTILIS		
2	3:23	4:27	64	SPORES 19659		
3	3:26	4:34	68	and9372 (ATTEST)		
4	3:29	4:30	61			
5	3:32	4:32	60			
6						
7	2:23	4:05	102			
8	2:28	4:07	99			
9	2:37	4:16	99			
10	2:47	4:09	81			
11	2:55	4:22	87			
12						
13	3:01	4:23	82			
14	3:05	4:20	75			
15	3:08	4:27	79			
16	3:10	4:24	74			
17	3:11	4:21	70			
18						
19						
20						
21						
22						
23						
24						
25						

REMARKS: Illinois Started w/ #6

SANITEC INC.

SANITEC MICROWAVE DISINFECTION UNIT HG-A 100S - MICROBIOLOGICAL TEST

UNIT NAME: HG-A 100-S
UNIT NUMBER: #1
UNIT LOCATION: SAFEWAY, CT

TEST DATE: 7/20/93
TEST START: 2:20 pm
TEST COMPLETE: 4:35pm

T = 0 =

TIME(MIN.)	STEAM TEMP. (C)	MWS INLET TEMP. (C)	MWS EXIT TEMP. (C)	THS OUTLET TEMP. (C)	NOTES
0	155	104	101	96	
5	151	103	104	96	
10	151	103	104	96	
15	153	104	105	96	
20	150	104	104	96	
25	150	104	104	96	
30	151	104	105	96	
35	151	104	105	96	
40	151	104	105	97	
45	152	104	105	101	
50	153	104	105	102	
55	159	103	103	102	
60	162	103	103	101	
65	155	104	103	101	
70	146	104	103	101	
75	153	104	103	101	
80	150	104	103	101	
85	153	104	104	101	
90	153	104	103	101	
95	150	103	103	101	
100	162	103	102	101	
105	162	103	103	102	
110	162	103	103	102	
115	162	104	103	102	
120	161	101	103	102	
125	158	101	102	101	

REMARKS:

130	157	103	102	102
135	157	103	102	101

SECTION V

APPENDIX

d) Application for renewal of an experimental permit must be submitted to the Agency at least ninety (90) days prior to the expiration of the existing permit. To the extent the information to be supplied for renewal is identical with that contained in the prior permit application, the applicant shall so note on the renewal application, and the Agency shall not require the resubmittal of data and information previously supplied to it.

e) A report must be submitted at the end of the experimental permit period, or as required by the Agency, which includes, at a minimum, the following:

1) A summary of operating data, including results of the Initial Efficacy Test(s) or Periodic Verification Test(s);

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

4) A demonstration that the infectious potential has been eliminated.

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

All PIMW treatment units must demonstrate that the infectious potential has been eliminated by using an Initial Efficacy Test in accordance with this Appendix.

This Option 1 is for a treatment unit that compromises the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection).

The purpose of this Phase 1 is to determine the dilution of each test microorganism from the treatment unit for each challenge load (Types A through C) identified in Table C of this Appendix.

a) Prepare and sterilize by autoclaving, two (2) challenge loads of Type A as identified in Table C of this Appendix. Reserve one (1) challenge load for Phase 2.

b) Each test microorganism must be processed in separate runs through the treatment unit. Prior to each run, the number of viable test microorganisms in each container must be determined in accordance with applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

c) Processing of the PIMW must occur within thirty (30) minutes after introducing the container of test microorganisms into the treatment unit.

d) The container of test microorganisms and challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s), an equal volume of liquid (e.g., sterile saline solution (0.9%, volume/volume), phosphate buffer solution, or tapwater) must be substituted in place of the chemical disinfectant(s).

e) A minimum of five (5) representative grab samples must be taken from the processed residue of each challenge load in accordance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846), incorporated by reference at 35 Ill. Adm. Code 1420.103. The number of viable test microorganisms in each grab sample must be determined in accordance with applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

f) Calculate the effect of dilution for the treatment unit as follows:

$SA = \text{Log } NoA - \text{Log } N1A$; where $\text{Log } N1A \geq 6$

where: SA is the log of the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) that were not recovered after processing challenge load Type A.

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) introduced into the treatment unit for challenge load Type A.

N1A is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) remaining in the processed residue for challenge load Type A.

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is ≥ 6. NoA is the inoculum size for challenge load Type A in Phase 2 below.

g) Repeat steps (a) through (f) in Phase 1 for challenge loads of PIMW for Types B and C identified in Table C of this Appendix to determine the effect of dilution (SB and SC, respectively).

The purpose of this Phase 2 is to determine the log kill of each test microorganism in each challenge load (Types A through C) identified in Table C of this Appendix.

a) Using the inoculum size (NoA) determined in Phase 1 above, repeat Phase 1 steps (a) through (e) under the same operating parameters, except that the physical and/or chemical agents designed to kill the test microorganisms must be used.

b) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum, as follows:

$$LA = \text{Log } NoA - SA - \text{Log } N2A \geq 6$$

where: LA is the log kill of the test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) after treatment in the challenge load Type A.

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) introduced into the treatment unit as the inoculum for challenge load Type A as determined in Phase 1 above.

SA is the log of the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) that were not recovered after processing the challenge load Type A in Phase 1 above.

N2A is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) remaining in the treated residue for challenge load Type A.

c) Repeat steps (a) through (b) in Phase 2 for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

This Option 2 is for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaves).

a) One microbiological indicator assay containing one of the test microorganisms at numbers greater than one million (1,000,000) must be placed in a sealed container that remains intact during treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s). The vial(s) must only contain the test microorganisms.

b) The container of test microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.

c) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum, as follows:

$$LA = \text{Log } No - \text{Log } N2A \geq 6$$

where: LA is the log kill of the test microorganisms (CFU and PFU) after treatment in challenge load Type A.

No is the number of viable test microorganisms (CFU and PFU) introduced into the treatment unit as the inoculum.

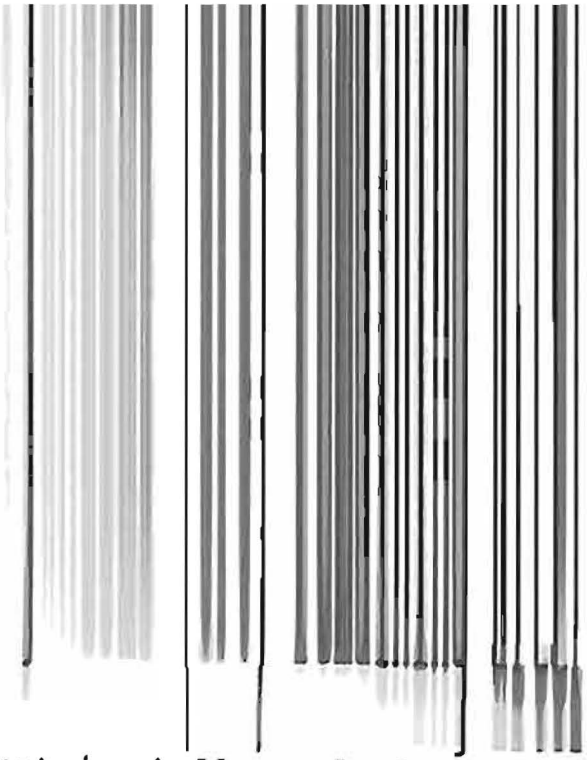
N2A is the number of viable test microorganisms (CFU and PFU) remaining after treatment in challenge load Type A.

d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

This Option 3 is for a treatment unit that uses thermal treatment and maintains the integrity of the container of indicator microorganism spores (e.g., autoclaves and incinerators).

a) One microbiological indicator assay containing at least one million (1,000,000) spores of one of the indicator microorganisms listed in Table B of this Appendix must be placed in a sealed container that remains intact during treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s). The vial must contain only the indicator microorganism vial.

b) The container of indicator microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.



treatment in challenge load Type A.

d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

Section 1422.APPENDIX A: Initial Efficacy Test Procedures
Table A: Test Microorganisms

1. Staphylococcus aureus (ATCC 6538)

2. Pseudomonas aeruginosa (ATCC 15442)

3. Candida albicans (ATCC 18804)

4. Trichophyton mentagrophytes (ATCC 9533)

5. MS-2 Bacteriophage (ATCC 15597-B1)

6. Mycobacterium smegmatis (ATCC 14468)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures
Table B: Indicator Microorganisms

1. Bacillus subtilis (ATCC 19659)

2. Bacillus stearothermophilus (ATCC 7953)

3. Bacillus pumilus (ATCC 27142)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures
Table C: Challenge Loads

This table identifies the three types of challenge loads of PIMW that must be used as part of the Initial Efficacy Test and Periodic Verification Test(s).

COMPOSITION OF CHALLENGE LOADS
% (w/w)

	A	B	C
Moisture	≤5	≥50	-----
Organic	-----	-----	≥70

Section 1422.APPENDIX B: Correlating Periodic Verification Test Procedures

a) A certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores is introduced into each challenge load as identified in Table C of Appendix A.

b) The test microorganisms and indicator microorganism spores must be placed in a sealed container that remains intact during treatment.

c) The container must be placed in each challenge load to simulate the worst case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the test microorganisms and indicator microorganism spores container within a sharps container that must in turn be deposited in a plastic biohazard bag that is then located centrally within the treatment unit.

d) The effectiveness of the treatment unit is demonstrated by calculating the log kill (L) of the test microorganisms in accordance with Option 2 of Appendix A of this Part. The equivalent log kill (T) of the indicator microorganism spores is calculated by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum as follows:

$TA = \text{Log No} - \text{Log N2A} \geq 3$

where: TA is the equivalent log kill of the viable indicator microorganisms (CFU) after treatment in challenge load Type A.

A. Introduction - Process Description

The Sanitec Microwave Disinfection Unit (MDU) is designed to shred and disinfect biomedical waste. When operated in accordance with all of Sanitec's written procedures and instructions, properly operated systems will render biomedical waste disinfected, generally unrecognizable, and of no greater risk to the public health than (normally associated with) residential household waste.

The disinfection process is computer controlled. Under normal operating conditions (automatic mode), operators need only charge the system with biomedical waste. The Unit has a hydraulic lift mechanism to hoist waste containers and drop waste into a hopper on top of the unit. The hopper has a sealed lid that opens and closes automatically. Inside the hopper, the bags and boxes of waste are directed towards a shredding device by a feed arm. The feed arm assists in forcing material into the shredder. Sensors monitor the amount of material moving into the hopper. Shredded material falls onto an auger-driven conveyor. As the waste enters the auger-driven conveyor, 150^0C (300^0F) steam is injected and conveyed through the microwave conveyor section. A series of microwave generators input energy to maintain uniform heating of the waste at a minimum temperature of 95^0C (203^0F). The waste is then transported to a Temperature Holding Section. The final temperature and time profile is a minimum of 95^0C (203^0F) for 30 minutes. The final waste product then falls into a dumpster or similar waste transport container that may be used to transport the disinfected waste to a repository.

B. Purpose

1. The purpose of validation testing is to monitor the initial effectiveness of the microwave disinfection process. Sanitec recommends that validation testing be performed after the unit is initially installed and operational or as may be directed by a State or government regulatory agency.

C. Performance Specifications

1. Capacity: minimum average of 1800 lb/hr (818 kg/hr). The capacity of the unit is based on the following data:

Waste Specifications:

Specific Weight:	11 lb/ft^3 (0.176 kilogram/liter)
Specific heat:	0.0597 Btu/lb-^{0}F (249.95 Joule/kilogram-°C)
Moisture:	Should be less than 10% of weight. If liquid content is higher than 10% (by weight), greater heat input will be needed and the volume capacity will to be reduced correspondingly by a decrease in auger rpm which is controlled by the process control system.

Metallic Content:	Stainless steel, tramp metal, surgical instruments, and other heavy metal items shall not be present in the waste to protect the wear life of the shredding system. However, there are no process limitations on syringes, needles, or similar items, except that this material should be processed with non-sharps material to ensure that it is generally no longer recognizable as medical waste.
Material Size:	The largest rigid piece size should be not larger than 0.385m x 0.385m x 0.385m (15" x 15" x 15").
Exclusions:	Radioactive/Bulk Cytotoxic/Chemical wastes and gross anatomical items shall not be processed in the Unit.

NOTE: The Sanitec MDU is capable of handling most categories of medical waste including general waste, lab waste, cultures and stocks, body fluids, sharps, animal bedding, animal carcasses, human pathological waste and trace chemotherapeutic waste that meet the USEPA's empty container definition.

Large stainless steel surgical instruments; implants such as pins, rods, joints, and other prostheses; and tools and broken pieces of hospital equipment should be segregated out to prolong the life of the shredder and capacity performance of the Unit. Laundry material and unusual quantities of paper material may adversely affect the overall capacity performance of the Unit.

D. Temperature and Time

1. The average temperature of the in-feed waste shall not be less than 0^0C (32^0F).

2. The input steam temperature shall not be less than 150^0C (300^0F).

3. The Microwave Section (MWS) inlet temperature shall not be less than 95^0C (203^0F). The Temperature Holding Section (THS) exit temperature shall not be less than 95^0C (203^0F).

E. Water Consumption

1. The waste material is heated and moistened by injected steam. The steam consumption will not be less than 35 kg/hr (77 lbs/hr, 9.3 gal / hr). This equates to about 15% by weight of the waste material throughput.

F. Microbiological Testing

1. This section describes the microbiological testing procedure for the initial quality assurance of the Sanitec MDU. The objective of the testing is to demonstrate, under actual load conditions, disinfection using a biological indicator, Bacillus atrophaeus

2. Sanitec recommends that tests be conducted with "Attest" self-contained biological indicators. The biological indicator is available through 3M, Medical Products Division, St. Paul, Minnesota, under the product number 1264 or equal. The product consists of a dry spore strip containing spores of Bacillus subtilis. Growth medium is contained in a crushable ampule. The medium is a modified Tryptic Soy broth with a pH-sensitive indicator dye (bromthymol blue). A flexible polypropylene vial holds the dry spore strip and the medium ampule. A green polypropylene cap containing a hydrophobic filter (Tyvek) covers the vial. The chemical indicator changes color in the presence of bacteria.

   Test ampules have the following characteristics:

   Bacillus atrophaeus var. niger ATCC 9372

   Population (mean/strip) = 3.6×10^6 Colony Forming Units (CFU)

G. Test Procedure

1. Before the test, the operating conditions of the Unit are to conform to the specifications and operating manual.

2. A validation test will consist of ten (10) biological indicators. Each biological indicator will be placed into a brightly colored sack, and numbered with a waterproof marker for easy retrieval.

   Samples are to be inserted, at 30 second intervals, through a cylindrical port located at the transfer hopper. This port is after the shredder and before the steam injection points and microwave generators. In addition to the samples to be disinfected in the unit, two untreated "control" samples of the biological indicator are to be processed in the same manner as the test samples, with the exception of not being introduced into the MDU. These will serve as active controls to ensure that the indicators are not inadvertently killed by some other step in the processing.

3. During the test procedure, the following data will be recorded:

   - Date
   - Name of responsible test manager
   - Biological indicator, source (supplier), and lot number
   - Insertion time of each sample into the Unit
   - Discharge time of each sample from the Unit

- Temperatures of the following areas recorded at five (5) minute intervals

  a. MWS inlet
  b. MWS exit
  c. THS exit
  d. Steam

- Additional remarks, observations, or comments

4. All biological indicators will be retrieved from the discharge area, i.e. solid waste container. Biological indicators will be examined for any signs of damage (cracked, crushed, broken) and comments noted. Biological indicators will then be placed into a dry block (37^0F, 1^0C) or water bath (39^0F, 1^0C) for incubation. The dry block is designed to break the inner glass ampule as the plastic container is pushed into the heating block. An Attest Biological Incubator, Model No. 127, is a small portable system that can test 26 indicators and two controls. The incubator is available from 3M. A hand held device provides similar results when using a water bath.

   Biological indicators will be examined at regular intervals for any color change. The appearance of a yellow color indicates bacterial growth. No color change indicates an adequate disinfection process. The recommended incubation time is 48 hours.

H. Results

1. A successful test shall be at least 9 of 10 negative biological indicators (no color change).

2. Results will be recorded and maintained in a manner suitable for periodic inspection by any regulatory agency. If no test frequency is specified in local regulations or laws, Sanitec recommends a quarterly test with biological indicators as a check on the instrumentation and controls system parametric monitoring.

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

August 25, 2000

Joseph Delloiacovo, President
Sanitec, Inc.
23 Fairfield Place
West Caldwell, NJ 07006

Dear Mr. Delloiacovo:

This department has evaluated the efficacy test data from Sanitec, Inc., for approval of its Microwave HGA-250 Disinfectant Unit as an alternative regulated medical waste treatment system.

I am pleased to inform you that the Microwave HGA-250 Disinfectant Unit is approved, pursuant to Public Health Law Section 1389-dd (1) (d) and 10 NYCRR Subpart 70-2, for use in the treatment of regulated medical waste, including pathologic waste. This approval is granted for the specific system used in your efficacy studies and should not be construed as a general endorsement of the technology employed, or any other unit or system. Any modifications to the system will require separate approval of the department and may involve further efficacy testing.

This approval does not relieve Sanitec, Inc. or any person using your system, from obtaining any other approvals which may be required by other laws or regulations.

Sincerely,

Lawrence S. Sturman

Lawrence S. Sturman, M.D., Ph.D.
Director, Wadsworth Center

STATE OF FLORIDA
DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

October 4, 1991

Mr. Joseph Delloiacovo
Vice President
ABB Sanitec, Inc.
Wayne Interchange Plaza II
155 Route 46 West
Wayne, N.J. 07470

Dear Mr. Delloiacovo:

This is in response to your application for use of the ABB Sanitec Microwave System as an alternative treatment method for biohazardous (infectious) waste.

After careful review of the information provided by ABB Sanitec, Safe Way Disposal Systems, Inc., and Frank Sheu, the microwave treatment process for biohazardous waste, with conditions, appears to meet the intent of Chapter 10D-104, Florida Administrative Code, for an alternative treatment method. The conditions for use in Florida are as follows:

1. The validation of newly installed microwave units shall be in accordance with the ABB Sanitec HG-A-250-S Microwave Disinfection Unit Validation Protocol. Results shall be kept on file at the treatment facility for three years and shall be available for review by HRS.

2. Efficacy of the unit shall be monitored after every 40 hours of unit use. The efficacy protocol shall be in accordance with the ABB Sanitec HG-A-250-S Microwave Disinfection Unit Challenge Protocol. Results shall be kept on file for three years and be available for review by the department.

3. Liquid waste must be either discharged directly into a sanitary sewer or contained within the treated material.

4. Backflow preventers (check flow devices) shall be installed on the inflow line to the pump or outflow lines of the spray units.

5. The unit shall be disinfected prior to maintenance.

6. Records of servicing, both maintenance and emergency, shall be kept for three years and be available for review by the department.

7. The microwave unit shall meet the FDA Performance Standards found in 21CFR Part 1030 and shall meet ANSI's operating guidelines contained in ANSI C-95.1. Personnel from the HRS Office of Radiation Control shall be allowed access to inspect the microwave operation for compliance with the ANSI standard.

8. The final endproduct shall be managed and disposed of per subparagraph 17-712.430(1)(b)5, Florida Administrative Code. The phrase "Treated Biohazardous Waste" shall be used in lieu of the phrase outlined in the referenced subparagraph.

9. Misuse or misrepresentation of this product may result in the cancellation of the approval as an alternative treatment method in Florida.

If you have any questions, please write me or call Francis W. Stanton, R.S., at 904/488-4070.

Sincerely,

Richard Hunter, Ph.D.
Assistant Health Officer for
Environmental Health

cc: T. Moore, DER
F. Stanton, R.S., HRS

State of California—Health and Human Services Agency

Department of Health Services

California
Department of
Health Services
SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

August 18, 2006

James Harkess, President/CEO
Sanitec USA, Inc.
9065 Norris Avenue
Sun Valley, CA 91352

Dear Mr. Harkess:

TREATMENT OF PATHOLOGY WASTE IN THE SANITEC MICROWAVE DISINFECTION SYSTEM AT THE SANITEC USA, INC. FACILITY IN SUN VALLEY, CALIFORNIA

The Department has reviewed your submittal proposing to treat pathology waste, including avian carcasses, at the Sun Valley, CA facility using the Sanitec Microwave System, an approved alternative medical waste treatment technology. The data presented to the Department appears to demonstrate efficacy in treating pathology waste, including avian carcasses, when the unit is operated under the conditions and restrictions specified in the Revision of Alternative Medical Waste Treatment System approval letter dated August 18, 2006, for the Sanitec Microwave Disinfection System.

If you wish to discuss this matter further, or have questions, please contact Steve Kubo at (916) 449-5684 or by email at skubo@dhs.ca.gov.

Sincerely,

Ronald Pilorin, Chief
Emergency, Restoration, &
Waste Management Section

Cc: Steve Kubo

NCDENR

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary

December 1, 2006

Ed Krisunias, MT (ASCP), CIC, MPH
WNWN International, Inc.
PO Box 1164
Burlington, Connecticut
USA

Dear Ed Krisunias;

This is in response to your letter requesting approval of the Sanitec unit for treatment of pathological wastes. At present, the only treatment approved for pathological wastes in North Carolina is incineration.

The Sanitec unit uses a combination of shredding and microwave radiation, to treat most regulated medical wastes. Regulated medical waste is defined as pathological, microbiological, and containers of blood and body fluids in excess of 20ml (eg. suction canisters).

Medical waste that is not regulated medical waste include items such as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required for such items before disposal in the general waste stream, therefore approval to treat such waste is not required by the Solid Waste Section.

In documents and test reports submitted to the Department, the Sanitec unit demonstrated effective treatment of test organisms. The unit is approved for the treatment of pathological waste as long as the unit is operated at the manufacturer's stated parameters.

Pathological wastes are defined as the tissues, organs, and body parts of humans and the carcasses of animals known or suspected to have died from a disease which is transmissible to humans.

Fetal remains may not be processed through the unit.

Should you have any questions regarding this matter you may contact me at (919) 508- 8499.

Sincerely,

Ellen B Lorscheider

Ellen Lorscheider
Environmental Programs Manager
Solid Waste Section

SAFETY SUMMARY – ATTACHMENT VI

1. Introduction

The following general safety recommendations shall be followed when performing maintenance on, making adjustments to or servicing the different systems and components of the Sanitec Microwave Disinfection Unit (MDU). Adhere to all engineering and work practice controls as described in your facilities policies and procedures manual for complying with Occupational Safety and Health Administration (OSHA) Standards.

2. Specific Recommendations

A. Biomedical Waste

1. **The microwave unit is designed to disinfect medical waste.**
2. **Exposure to biomedical waste can occur in instances but are not limited to when entering the infeed hopper to clear a shredder blockage or when repairing the primary shredder.**
3. **When handling biomedical waste wear Personal Protective Equipment (PPE) as recommended by OSHA. At a minimum, operators should wear rubber or latex gloves inside of leather or puncture resistant gloves.**

   PPE may include:

   a. **Safety glasses or goggles**
   b. **Appropriate covering for clothing/body, (e.g. Tyvek Suit)**
   c. **Shoe covers**
   d. **Full face Air Purifying Respirator (APR) or Half-Face APR which meets or exceeds National Institute of Occupational and Health (NIOSH) specifications.**
   e. **Steel toe boots or shoes with impenetrable soles.**

   When a procedure is completed which involves exposure to biomedical waste, dispose of the contaminated clothing in the microwave unit (except the steel toe shoes).

2. Specific Recommendations - continued

B. Electrical Circuits

1. **The MDU operates on 400 volts. When performing electrical service all power contacts shall be locked out/tagged out according to operating facility policy.**
2. **Never make adjustments to equipment when the power is on. Under certain conditions danger may still exist when the power is off due to charges retained by capacitors. This is especially true of the microwave generators. To avoid injury disconnect power and allow circuits to discharge before handling.**

C. Mechanical Safety

1. **Various aspects of the unit involve mechanical components. These components (e.g., drive belts, hydraulic compressors and lifting mechanisms to name a few) have the potential to cause injury.**
2. **All guards must be kept in place and in a secure fashion. When guards are removed for servicing the facilities electrical lockout/tagout policy should be instituted.**
3. **Mechanical components should be maintained according to manufacturers instructions to minimize malfunctions and risks to employees.**
4. **When performing maintenance or troubleshooting operations on the primary shredder or granulator which require exposure to moving parts of the equipment, such as blades, cutters, and/or tips, the primary shredder and granulator shall be disengaged by switching the main control panel disconnect switch (located on the right side of the control panel) to the off position and padlocked.**

D. Steam

1. **The unit utilizes an electric steam generator which produces steam temperatures at approximately 300°F. This temperature steam can cause severe bums. All hot surfaces and steam pipes are labeled to indicate such. Exercise caution when working around these areas.**

2. Specific Recommendations - continued

E. Microwave Safety

1. The microwave generators used in the MDU are similar to those used in consumer microwave ovens.

a. All microwave generators shall be checked on a daily basis for leakage. The MDU shall be in automatic operation and the RF lamp on the microwave generator must be illuminated (the microwave screw must be turning) to determine if there is any leakage.

b. Meters used to check for leakage shall be set at 10 mw/cm^2 or 5 mw/cm^2 as required by the state. The OSHA Permissible Exposure Limit (PEL) is 10 mw/cm^2 averaged over six minutes or 0.1 hour.

2. If any leakage is detected, the user is required to report in writing to Sanitec the following information.

a. Sanitec unit number

b. Microwave generator and serial number

c. Microwave generator hour readings

d. Leakage reading and method of measurement

e. Corrective actions

f. Follow up readings

3. The outside of the MDU is labeled to indicate the presence of microwave generator operation.

3. Specific Safety Procedures

A. Infeed Hopper/Shredder Blockage

1. The facility mandated PPE shall be worn. This may include:

a. Safety glasses or goggles

b. Appropriate covering for clothing/body, (e.g. Tyvek Suit)

3. Specific Safety Procedures - continued

c. Shoe covers

d. Full Face Air Purifying Respirator (APR) or Half-Face APR which meets or exceeds National Institute of Occupational and Health (NiOSH) specifications.

e. Steel toe boots or shoes with Impenetrable soles.

2. Evaluation of problem in hopper (without hopper entry)

a. Raise hopper flap

b. Conduct a visual inspection. All bagged material and loose waste can be removed by the use of long handled hooks or rakes to obtain a clear view of the shredder knives to determine the souce of the problem.

c. Care must always be exercised due to potential presence of microbiologically contaminated material and sharp items.

d. Loose waste should be bagged or boxed before being removed from the hopper.

NOTE

Do not enter the hopper if the nature of the blockage cannot be corrected by the methods described above. Return the hopper flap to the closed position and inject steam continuously for a period of no less than two (2) hours.

After this procedure has been completed, entry into the hopper can be performed. PPE should be worn to minimize contact with hot surfaces and other physical hazards.

Never enter the hopper when alone. A second person should always be present to assist and ensure that the safety procedures are maintained. The main control panel disconnect switch (located on the right side of the control panel) shall be switched to > the off position and padlocked.

B. Removal of the HEPA filter.

1. The facility mandated PPE shall be worn.

a. Tyvek Suit

b. Rubber or latex gloves

c. Full face or half face respirator

d. Goggles or safety glasses

2. Remove cover plate and remove HEPA filter. Place filter into a bag and dispose of according to facility policy. Avoid dropping or shaking the filter.

ALL SAFETY CONCERNS SHALL BE DIRECTED TO THE FACILITIES SAFETY PROGRAM DIRECTORY