FEE SHEET FOR MEDICAL WASTE PERMITS

ADEM No.: 60139

Applicant: BioLife Testing Laboratory-Hoover

Location: 2197 Parkway Lake Dr
Hoover, AL 35244

County: Jefferson

State: Alabama

Permit No.: TRTS 052824-0101

Date Application Received: 05/28/24

Permit Fees Required	Initial Issuance	Modification	Reissuance	Total
New Technology Review	$10,205	-	-	
Commercial Treatment Facility	$16,460	$7,280	$9,180	$16,460
Commercial Transportation of Medical Waste	$3,490	$1,460	$2,035	
Storage of Untreated Medical Waste	$2,630	$665	$1,960	

Additional Fees				
Geological Review	$4,055	$2,730	$2,730	
Solid Waste Disposal Notification	$180	$180	$180	
Greenfield Fee	$1,610	-	-	$1,610
Variance Request	$1,215	-	-	

	Total Fee Due:	$18,070
Check No.: 3387004207	Amount Submitted with Application:	$18,070
	Amount Received:	
	Amount to be Billed:	
Permits & Services	Amount Received:	
	Date Received: JSmith	06/05/2024
	Amount to be Refunded:	
	ADEM Fund Code:	422

RECEIVED
JUN 05 2024
ADEM
EDDS

$ ck "3387004207"

Fee Schedule Prepared by: ASP Date: 06/05/24

Fee Schedule Reviewed by: _____ Date: _____

00220131933387004207

PAGE: 1 of 1

Takeda Pharmaceuticals USA, Inc.
Pay On Behalf Of
BioLife Plasma Services L.P.
730 Stockton Drive
Exton, PA 19341

DATE: May 17, 2024
CHECK NUMBER: 3387004207
AMOUNT PAID: $18,070.00

RECEIVED

JUN 05 2024

ADEM
EDDS

00007 10279 CKS SD 24136 - 3387004207 NNNNNNNNNNN 1365100004203 X41108 C
ALABAMA DEPARTMENT OF ENVIRONMENTAL
MANAGEMENT
PO BOX 301463
MONTGOMERY AL 36110

Date	Invoice Number	Description	Gross Amount	Discount	Net Amount
05/01/24	PERMITHOOVER2024		$18,070.00	$0.00	$18,070.00
		TOTALS	**$18,070.00**	**$0.00**	**$18,070.00**

PLEASE DETACH BEFORE DEPOSITING CHECK

Takeda Pharmaceuticals USA, Inc.
Pay On Behalf Of
BioLife Plasma Services L.P.
730 Stockton Drive
Exton, PA 19341

CHECK NUMBER 3387004207

May 17, 2024

50-937
213

PAY TO THE ORDER OF: ALABAMA DEPARTMENT OF ENVIRONMENTAL
MANAGEMENT
PO BOX 301463
MONTGOMERY, AL 36110

CHECK AMOUNT
$18,070.00

EXACTLY *********18,070 DOLLARS AND 00 CENTS

Security features included. Details on back.

JPMorgan Chase Bank, N.A.
Syracuse, NY

Authorized Signature

[redacted] [redacted]

ADEM

Medical Waste Treatment Permit Application

(Print or Type)

A. Treatment Facility Identification:

Name of facility: BioLife Testing Laboratory - Hoover

Contact person: Trysh Pierce

Title of contact person: Facility Manager Email Address: patricia.pierce@takeda.com

Mailing address: 2197 Parkway Lake Dr.

City: Hoover State: AL Zip Code: 35244

Business address: 2197 Parkway Lake Dr.

City: Hoover State: AL Zip Code: 35244

Business telephone number: (205) 403-9656

Emergency/after-hours number: (251) 510-4177

Has medical waste been previously treated at this site? Yes _____ No X

If yes, what type of technology was utilized? N/A

What date did the last waste treatment occur? N/A

Name and mailing address of property owner if different from applicant:

Name of property owner: BioLife Plasma Services, LP

Mailing address: 1200 Lakeside Dr

City: Bannockburn State: IL Zip Code: 60015

Owner's telephone number: (877) 432-5820

B. Permit Status: (Check one)

X First Application

___ Permit renewal: Permit No. _____

Expiration date of current permit: _____/_____/_____

___ Permit Modification: Provide a narrative description of the modifications sought, listing the Section(s) of the existing permit to be modified, and the rationale for the request to modify the permit.

C. Treatment Method:

1. Steam Sterilization

   Cycle Operating Parameters: 30 Minutes; 250 °F Temp; Pressure, 15 psi

2. Other Treatment Method: (Specify, include Letter of approval) See attached Approval Letter

D. Attachments: (The application will not be reviewed unless all attachments are submitted)

1. Medical Waste Management Plan
2. Applicable fees
3. A detailed floor plan of the facility showing all handling, storage and treatment equipment.
4. List equipment (including shredders) utilized in treatment of medical waste. Include model numbers, manufacturers, number of years in use, certifications, number of pieces, etc. (Attach sheets as necessary)

[Note: ADEM Form 412, Medical Waste Treatment Permit Application, is not complete without payment of all the appropriate fees specified in Chapter 335-1-6 of the ADEM Administrative Code.]

DI. Certification: (To be signed by a responsible official)

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Signature: Kathryn Barrett

Typed name: Kathryn Barrett

Official Title: VS Lab Operations Director

Date: 5-13-2024

Please submit two copies of each Application and attachments to:

Alabama Department of Environmental Management

(Mailing Address):
Environmental Services Branch
Land Division
P.O. Box 301463
Montgomery, AL 36130-1463

(Street Address):
Environmental Services Branch
Land Division
1400 Coliseum Boulevard
Montgomery, AL 36110-2059

Phone: 334-271-7984

Fax: 334-279-3050

Make all checks payable to the Alabama Department of Environmental Management

STANDARD OPERATING PROCEDURE

SOP Number:	SOP-244167	**Page:**	**1 of 14**
Version Number:	3.0		
Parent Document:	N/A		
SOP Title:	**BTL-US Regulated Medical Waste Plan**		

PURPOSE

The purpose of this Standard Operating procedure (SOP) is to establish procedures for the safe handling and proper disposal of regulated medical waste to include segregation, packaging, labeling, storage, treatment, and transportation in compliance with all local, state, and federal laws.

SCOPE

Functional Areas, Job Functions	This SOP addresses the procedures for Regulated Medical Waste within the BioLife Testing Laboratories (BTL-US).
Applications	This SOP applies to the BTL-US.
Limitations	This SOP does not apply to BioLife Centers or BioLife Headquarters. Sections 10 and 11 for on-site processing and bin-washing apply to BTL-AL only.

RESPONSIBLE PARTIES

Procedures are to be performed by staff as directed within the procedural steps below. The Laboratory Managers and Laboratory Supervisors will be available for consultation and will assume responsibility for overseeing the competent performance of the procedure.

EQUIPMENT / MATERIALS:

BTL Bloodborne Pathogen Response Kit
Preparation of Working Solutions of Bleach
Emergency Contact List BTL-AL
Emergency Contact List BTL-GA

DEFINITIONS:

Department of Transportation (DOT) – The federal agency that regulates the safe transport of regulated medical waste on public roads; Hazardous Materials Regulations.

EHS – Environmental Health and Safety.

Non-regulated Medical Waste – All disposable items that do not meet the definition of regulated medical waste as defined in the General Information section of the document, including, but not limited to, urine, urine cups, thermometer sheaths, slightly soiled bandages, cotton balls, gauze, packaging materials, etc.

Occupational Safety and Health Administration (OSHA) – The federal agency that regulates the safe handling and disposal of regulated medical waste generated within the facility.

OPIM – Other Potentially Infectious Materials.

PPE – Personal Protective Equipment.

Regulated Medical Waste – A term generally synonymous with infectious waste and is regulated by Occupational Safety and Health Administration (OSHA), Department of Transportation (DOT), and the state in which the facility operates.

Saturated - A material that is "soaked to capacity" with blood or OPIM from which liquid drips freely or can release dried blood flakes into the environment when handled or compressed.

State Agency– The agency within a state that governs the safe handling, storage, and disposal of regulated medical waste including the Department of Health, Department of Natural Resources and/or the state Environmental Protection Agency.

GENERAL INFORMATION:

OSHA defines regulated medical waste as:

All disposable articles generated in the laboratory that are ***saturated*** with blood, plasma, serum or body fluids per OSHA definition, are regulated specifically by the state or identified by a specific lab SOP, will be handled as regulated medical waste. These articles are classified as sharps and non-sharps. Do not discard non-regulated waste into regulated medical waste containers (biowaste containers).

1. Liquid or semi liquid blood or other potentially infectious materials (OPIM); other potentially infectious materials includes: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids,

2. Contaminated items that would release blood or other potentially infectious materials in a liquid or semi liquid state if compressed (these are items that are saturated with blood or OPIM),

3. Items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling,

4. Contaminated sharps, and

5. Pathological and microbiological wastes containing blood or other potentially infectious materials (OPIM).

RESPONSIBILITIES AND PROCEDURE

1.0 Train Staff on Regulated Medical Waste Management (Trained Staff)

1.1 Train all employees that handle and/or treat medical waste in the proper management of regulated medical waste prior to assignment to a work area.

1.2 Reinforce training by reviewing proper management of regulated medical waste during regularly scheduled staff meetings and training sessions.

1.3 Review training with each employee annually and whenever necessary to reflect new or modified tasks and procedures.

1.4 Document training.

2.0 Identify and Segregate Regulated Medical Waste (Trained Staff)

2.1 Identify and segregate regulated medical waste from other waste at the point of origin into the proper container.

The "point of origin" is identified as the room or area where the regulated medical waste is generated.

2.2 Never retrieve an item from a sharp's container or biohazardous waste container. Immediately notify management of the situation. Contact Supervisor for guidance if equipment falls into a bin.

2.3 Wear buttoned lab coat, safety glasses and mask, or face shield, and gloves when handling medical waste.

2.4 Inspect bin for damage prior to putting into use at point of origin.

2.4.1 If damaged, tag and set aside for removal by Lab Management or contracted vendor.

2.5 Enclose bagged, regulated medical waste prepared for off-site transport in a rigid type container or approved cardboard container.

3.0 Dispose Regulated Medical Waste (Trained Staff)

3.1 Use appropriate biohazardous waste containers for containment of regulated medical waste.

Biohazardous waste containers are provided by contracted regulated waste hauler if the waste will be treated offsite.

3.2 Utilize the following types of biohazard waste containers in the laboratory:

3.2.1 Bags – Single use

3.2.1.1 Collect and store regulated medical waste in impermeable, red, polyethylene or polypropylene plastic bags. Bags must be constructed of

polychlorinated-free filler plastics that meet impact and tear resistant standards as required by State and Federal Regulations.

3.2.1.2 Utilize a “double-bag” method in regulated medical waste containers when discarding sample tubes with plasma or OPIM that may leak. Additional absorbents or “chux” pads should be utilized in the bottom of the bag to prevent leaking of liquid regulated medical waste.

3.2.2 Quarantine Boxes/Reusable Containers

Biohazard containers should be moved to the regulated medical waste storage room when the container is no more than 2/3 full. If discarding sample caps or sample tubes containing plasma or OPIM, or similar heavy biohazardous waste, do not fill the container more than 1/2 full.

3.2.2.1 Collect, store, and transport regulated medical waste in barrels/tubs/push bins that are rigid, leak resistant, puncture resistant and constructed of smooth, easily cleanable, impermeable materials resistant to corrosion by disinfectant chemicals.

3.2.3 Cardboard Containers- Single use

3.2.3.1 Collect, store, and transport regulated medical waste in fiberboard containers.

3.2.3.2 Utilize a “double-bag” method in all cardboard bins to minimize risk of leakage.

3.2.4 Sharps Containers

3.2.4.1 Contain sharps in rigid, plastic biohazard sharps containers that are closable, puncture resistant, leak-proof on sides and bottom, and labeled or color-coded with applicable biohazard warning.

All biohazard sharps containers shall be closed at the point of origin when filled to the 2/3 line and placed inside a rigid barrel/tub/push bin or cardboard biohazardous container prior to in-house processing or sending offsite for processing.

4.0 Store Regulated Medical Waste Onsite (Trained Staff)

4.1 Store regulated medical waste in a fully enclosed room with walls and floors constructed of smooth, easily cleanable materials that are impervious to liquids. The storage area should include a ceiling and there should be no return air vents. The area must meet the following criteria:

4.1.1 Locate area away from pedestrian traffic with access restricted to authorized staff only (by signs, etc.) with the doors closed when not in use. The door of this storage area will also be identified with a sign that reads “Medical Waste”, or “Biohazardous” and display the International Biological Hazard Symbol.

4.1.2 Control pests to ensure area is vermin and insect free.

4.1.3 Clean and disinfect storage area routinely. (Janitorial Contractor)

4.1.3.1 Mop floor of storage area weekly with antiviral disinfectant.

4.1.4 Meet any other applicable regulations that prevent the transmission of disease or injury.

4.1.5 Store waste no more than seven (7) days unless waste is refrigerated below 45 degrees (F).

If state regulations are more stringent than requirement above, adhere to the state regulations for storage.

5.0 Label Regulated Medical Waste for Off-Site Treatment (Trained Staff)

The equipment used in Confirmatory Testing utilizes waste bottles to collect liquid waste. Liquid waste collected in the waste bottles is decontaminated with a bleach solution prior to disposal. The waste bottles must be identified as “biohazardous waste” with a biohazard label or sticker.

5.1 Confirm the final package (fiberboard boxes and/or reusable tubs) are labeled with the required DOT labels.

5.2 Label exterior containers (fiberboard boxes, barrels or tubs) used to collect, store, or transport regulated medical waste for treatment with label providing the generator’s name and address.

5.2.1 Acquire labels from medical waste hauler for exterior containers that are generator-specific, such as bar codes or specific container numbers.

5.2.2 Check labels to ensure generator-specific labels provide the generator and medical waste hauler’s name, address, emergency telephone number, and registration number.

If generator-specific labels do not contain all of the information listed above, the laboratory may generate labels containing the necessary information.

5.2.3 Attach label to exterior container.

5.2.4 Date the affixed label with the date the container is packaged.

Exterior containers used to store and transport regulated medical waste must be labeled with the international biological hazard symbol of appropriate size as required by State and Federal Regulations.

5.3 Confirm the exterior container displays the proper shipping name “Regulated Medical Waste” and the shipping identification number “UN3291”.

If exterior labeling becomes damaged or illegible, contact contracted regulated waste hauler to replace labels or container.

6.0 Package Regulated Medical Waste (Trained Staff)

6.1 Fill the container and ensure the container closes properly without obstruction.

6.2 Gather and twist the top of the biohazard bag(s) and secure with a tie or single hand knot.

6.3 Seal the container.

6.4 Examine the exterior of the container to ensure the following:

6.4.1 Absence of dents or other damage that may affect the integrity of the container,

6.4.2 Absence of objects protruding from the walls or lids,

6.4.3 Absence of leaks, and;

6.4.4 Absence of waste residue on the outside of the container.

6.5 Place container in a secondary container before disposal, if the outside of the container is contaminated or the exterior is damaged.

6.6 If waste will be treated offsite, tag damaged bins and set aside for removal by regulated medical waste hauler.

7.0 Transport Regulated Medical Waste for Off-Site Treatment (Medical Waste Hauler)

7.1 Transport of registered medical waste must be performed by medical waste hauler operating in conjunction with local, state, and federal regulations and who perform the biohazardous waste pick-ups on a routine basis (i.e., daily or weekly scheduled pick-up).

7.2 Maintain packaged regulated medical waste, fully intact, until treatment.

7.3 Place all ruptured or leaking packages of regulated medical waste in a secondary container prior to off-site transport.

7.4 Dispose of regulated medical waste off-site with an approved disposal method such as incineration, autoclave, etc.

8.0 Generate Shipping Documentation for Off-Site Treatment (Medical Waste Hauler or Trained Staff)

8.1 Generate shipping paper documentation (Manifest) to accompany each shipment of regulated medical waste.

This document is the record of the type and quantity of waste offered for transport and includes the following information, legibly printed in English: Proper shipping name of the waste (Regulated Medical Waste), Hazard Classification (6.2), Shipping Identification number of the waste (UN3291), Packing group (PGII), and total volume/mass of containers in the shipment.

8.2 Sign shipping documentation before the medical waste hauler accepts a shipment.

Exception – Medical waste haulers may utilize an online manifest storage and retrieval system that is acceptable under state law. The online manifest will provide service date, container identification and description, weight, and method of destruction. To view the online manifest for the BioLife Testing Laboratory, visit https://ebpp.documentdna.com/stericycle/ and complete the registration process. The account numbers are listed below:

BTL-AL	3000956523
BTL-GA	3001064826

8.3 Maintain shipping documents received at time of waste pick-up by medical waste hauler in a labeled folder or binder.

9.0 Maintain Regulatory Requirements for On-Site Treatment (BioLife EHS or Trained Staff)

9.1 Medical waste is treated by steam sterilizers (autoclaves) provided the following requirements are met:

9.1.1 Medical waste does not contain hazardous chemicals or radioactive waste.

9.2 Certain medical waste, including sharps shall be further processed using a grinding method after the steam sterilization process.

9.3 Steam sterilizers are equipped to continuously monitor and record temperature and pressure during the entire length of each cycle.

9.3.1 Each bag or container is exposed to a minimum temperature of 250 degrees Fahrenheit and at least 15 pounds of pressure for 30 minutes.

9.3.2 Each sterilizer is evaluated for effectiveness under full loading by an approved method (i.e., biological indicator) at least once for each 40 hours of combined operation.

9.4 A log will be maintained for each steam sterilization unit and will contain the following:

9.4.1 The date, time (including duration), and operator for each cycle;

9.4.2 Approximate weight or volume of medical waste treated during each cycle;

9.4.3 The temperature and pressure maintained during each cycle;

9.4.4 Method utilized for confirmation of temperature and pressure; and

9.4.5 Dates and results of calibration and maintenance.

9.5 Containers used to transport treated waste offsite shall not be red in color or contain markings that would indicate the material is untreated waste.

10.0 Perform On-Site Treatment of Regulated Medical Waste (Trained Staff)

10.1 Transport filled biohazard container to regulated medical waste processing area (BioHazard Room).

10.2 Load biohazard container onto the sterilization device scale to capture container weight.

10.3 Move the biohazard container into the sterilization device lift compartment.

10.4 Ensure biohazard containers are secured within the lift compartment.

10.5 Exit lift compartment area and ensure area is clear of other staff and contractors.

10.6 Move to sterilization device control panel and press “start” control.

10.7 Remove the empty biohazard container from the lift compartment after the containers are returned to the “empty” position.

10.8 Place soiled biohazard container in queue for bin washing.

10.9 Repeat the loading and unloading of biohazard containers as needed to fill processed waste container.

10.10 Notify the Facilities Department of any issues or alarms on the sterilization equipment immediately.

10.11 Position a lid on the processed waste container once full and move to loading area behind the Biohazard Waste Processing Room.

10.12 Load the full bin of processed waste unto the awaiting trailer provided by the contracted advanced recycler.

A fully enclosed trailer will be placed at the loading dock to the exterior of the Biohazard Waste Processing Room for full containers of processed waste to be stored prior to removal from site.

10.13 Contact the contracted advanced recycler when the trailer is full and ready for pick-up.

10.14 Obtain a receipt of pick-up or invoice from the advanced recycler and store for 3 years onsite.

11.0 Perform On-Site Biohazard Container Cleaning (Trained Staff)

11.1 Add bin washing detergent to bin washer detergent container.

11.1.1 Determine appropriate amount of detergent for bin load from the detergent container instructions or detergent package insert.

11.2 Load empty, soiled biohazard containers – two containers per cycle – onto bin washer arms.

11.3 Ensure the clearance area around the bin washer arms is clear of other staff and contractors.

11.4 Move to bin washer device control panel and press “start” control.

11.5 Unload clean bins following completion of cleaning cycle and place in the designated “clean container” area.

11.6 Repeat process until all soiled biohazard containers are clean.

11.7 Notify the Facilities Department of any issues or alarms on the bin washer equipment immediately.

12.0 Contain Regulated Medical Waste (Trained Staff)

12.1 Clean surfaces contaminated with spilled or leaked regulated medical waste with industrial strength cleaner to remove visible soil before disinfecting.

12.1.1 Report all spills as a Safe Save (Near Miss) if no exposure (no contact with person, or only contact with clothing) occurred.

If a spill resulted in an exposure, refer to the Exposure Control Plan and report as a Safety Incident, if applicable.

12.1.2 For sample spills that prohibit completion of testing and thus require manual entry of results by lab office (e.g. no back-up available), open an Event record in addition to reporting as a Safety Event.

12.2 Take the following steps if a regulated medical waste spill occurs that exceeds a routine spill (i.e. spill that has spread out over a large portion of the floor):

12.2.1 Isolate the area from unauthorized persons.

12.2.2 Utilize the site-specific Emergency Contact List located on the spill kit to call for assistance if in-house staff cannot contain the spill.

12.2.2.1 Contact a team member listed in the “Facilities Related Emergency” contact information field.

12.2.2.2 Contact the appropriate local or state emergency department as needed

12.2.3 Post a “Caution, Wet Floor” sign to alert others of a potential slip area, if applicable (remove sign once the floor is decontaminated and dry).

12.2.4 Retrieve the BTL Bloodborne Pathogen Response Kit for large area regulated medical waste (i.e. plasma or whole blood) spills.

12.2.5 Don PPE located in the spill kit.

12.2.6 Tape off the perimeter area with barrier tape.

12.2.7 Apply an absorbent material (i.e. absorbent pads), if a “fluids” spill has occurred. Broken containers such as glassware or sharps must be picked up by mechanical means (i.e. dustpan and brush/broom). Collect absorbed waste and place all refuse in the appropriate biohazard waste container.

12.2.8 Clean and disinfect all non-disposable items with a bleach solution that contains approximately 5,300 ppm of chlorine or according to the manufacturer’s recommendation. If instruments were involved refer to manufacturer’s instructions for safe disinfecting. Treat all disposable items as regulated medical waste and place in an appropriate biohazard container.

Refer to Preparation of Working Solutions for Bleach for instructions in making a working solution of household bleach that contains approximately 5,300 ppm of chlorine.

12.2.9 Disinfect the area and all reusable supplies with the freshly prepared working solution of bleach described above, or another appropriate disinfectant.

12.2.10 Remove personal protective equipment and discard as regulated medical waste.

12.2.11 Seal medical waste container(s). Place in the biohazard storage area.

12.2.12 Wash hands, forearms, and face with soap and running water.

12.2.13 Notify Lab Management after using spill kit.

13.0 Maintain BTL Bloodborne Pathogen Response Kits (Trained Staff).

13.1 Maintain the BTL Bloodborne Pathogen Response kit to ensure adequate supplies are available in the event of a large area Regulated Medical Waste Spill.

13.1.1 Spill kits can be ordered from an approved vendor.

13.1.2 Attach an inspection tag to the spill kits for monthly inspections to be completed.

13.1.3 Secure the lid of the spill kit with tamper tape as a visual indicator for tampering or use.

13.1.4 Write the spill kit expiration date at top of inspection tag.

13.1.4.1 Initial and date.

13.1.5 Secure site-specific Emergency Contact List to the spill kit.

13.1.5.1 Secure Emergency Contact List BTL-AL to spill kits located in Hoover, AL.

13.1.5.2 Secure Emergency Contact List BTL-GA to spill kits located in Covington, GA.

13.2 Inspect the spill kits once per calendar month to ensure the tamper tape is still intact and the kit is not nearing expiration.

13.2.1 Notify Lab Management if the spill kit has been opened or tamper tape is no longer intact.

13.2.2 Notify Lab Management when spill kits are within 60 days of expiration.

13.3 Replace BTL Bloodborne Pathogen Response kits on an annual basis (+/- 30 days).

13.4 Replace the spill kits or supplies within the spill kit after use.

13.4.1 If supplies used can be replenished, add the supplies to the spill kit, close, and secure lid with tamper tape.

13.4.2 If supplies cannot be replenished, replace spill kit following instructions in 13.1.

REFERENCED DOCUMENTS

BioLife EHS&S SharePoint Site – Regulated Medical Waste Folder
BTL-US Exposure Control Plan
General Laboratory Policies
Preventive Maintenance of Confirmatory Testing Equipment

APPENDICES

1.	Appendix 1: Addendum for the BioLife Testing Laboratory in Hoover, Alabama. Includes information for treatment methods available onsite, contracted advanced recycler, and third-party contact, location, and permit information for services utilized to transport, store, treat, and disposal of regulated medical waste offsite. Training requirements are included for staff.

APPENDIX 1: ADDENDUM FOR THE BIOLIFE TESTING LABORATORY IN HOOVER, ALABAMA

1.1 Treatment method to be utilized onsite:

1.1.1 Thermal treatment using machine autoclave cutting sterilization device.

Confirmatory Testing collects liquid washer waste in a waste bottle attached to the equipment. Per instructions, a bleach solution is added to the waste bottle to disinfect the liquid waste prior to disposal.

1.1.2 ADEM Permit Number: XXXXXXXX (To be determined)

1.2 Contracted Advanced Recycler for waste post onsite treatment:

1.2.1 ACI Plastics, Inc.

Attn: M. Scott Melton

2945 Davidson Road

Flint, MI 48506

810-869-4970

1.3 Transporter of any untreated medical waste transported off-site:

1.3.1 Stericycle

1485 Hartman Industrial Blvd

Midfield, *AL* 35228

205- 598-1106

1.3.2 ADEM Permit Number: TRN 102391-GA02

1.4 Treatment/Processing facilities utilized:

1.4.1 None

1.5 Disposal facilities utilized:

1.5.1 Stericycle, Inc

1924 Joy Lake Road

Lake City, GA 30260-3658

1.5.2 Permittee: Stericycle, Inc – Lake City Facility

1.5.3 Georgia Department of Natural Resources permit number: 031-035P(INC)

1.6 Frequency of medical waste removal from the generator's facility:

1.6.1 Up to 10 times weekly

1.7 Training of employees

1.7.1 Each employee will complete training in accordance with good manufacturing practices regarding regulated medical waste including completing e-Learnings, reading written policies and procedures, and hands-on training with a designated trainer.

1.7.2 Individuals responsible for ensuring adequate training completion:

Training Manager

FEE SHEET FOR MEDICAL WASTE PERMITS

ADEM No.: _____

Applicant: BioLife Plasma Services

Location: 2197 Parkway Lake Drive

Hoover, Alabama 35244

County: Shelby

State: Alabama

Permit No.: _____

Date Application Received: _____

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Conf/Check No.:	Amount Received:	
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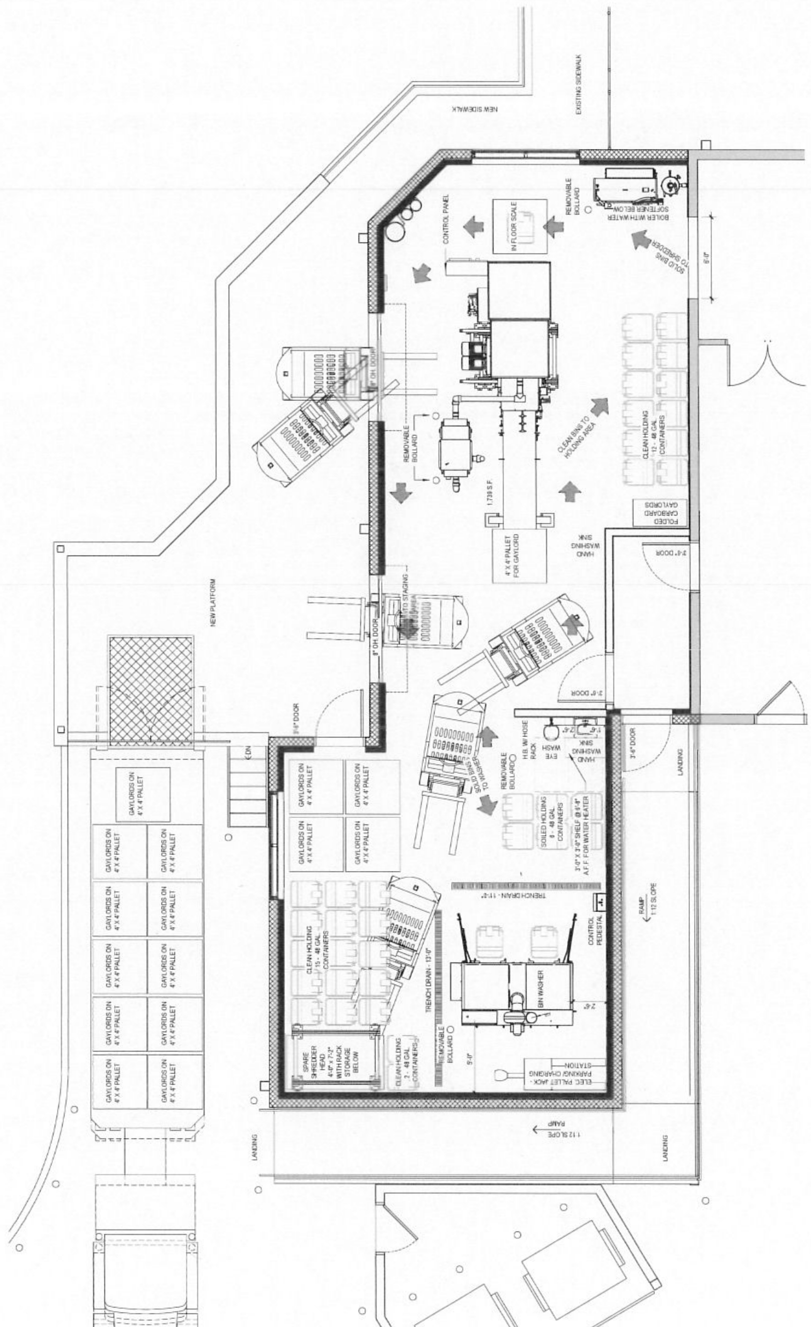
Permits & Services	Amount Received:	
	Date Received:	
	Amount to be Refunded:	
	ADEM Fund Code:	422

Fee Schedule Prepared by: ASPx7703 Date: _____

Fee Schedule Reviewed by: _____ Date: _____


NEW SIDEWALK
EXISTING SIDEWALK
REMOVABLE BOLLARD
IN FLOOR SCALE
CONTROL PANEL
CLEAN HOLDING 12 - 48 GAL CONTAINERS
CLEAN BINS TO HOLDING AREA
FOLDED CARBOARD GAYLORDS
HAND WASHING SINK
4' X 4' PALLET FOR GAYLORD
NEW PLATFORM
GAYLORDS ON 4' X 4' PALLET
BIN WASHER
CONTROL PEDESTAL
LANDING
RAMP 1:12 SLOPE

Equipment List for STI300 Process

Model: STI Chem-Clav Series 2000

Manufacturer: BioSAFE Engineering, LLC.

# of pieces: 1

New equipment at site. No years in use.

Bin Washer:

Unikon T1500 special 2408505

Manufacturer: Unikon

# of pieces: 1

New equipment at site. No years in use.

ADEM

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

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Education/Outreach: 213-4399

December 18, 1998

Mr. Randall G. McKee
Sterile Technology Industries, Inc
1155 Phoenixville Pike, Unit 105
West Chester, PA 19380

Dear Mr. McKee:

RE: Use of STI Chem-Clav Series 2000 Unit as an Alternative Treatment Technology

Pursuant to Rule 335-13-7-.08(3) the Department has reviewed the information submitted for the STI Chem-Clav Series 2000 Unit marketed by Sterile Technology Industries to treat regulated medical waste. This unit primarily utilizes sodium hypochlorite and low-pressure stream. Any use of the trade name mentioned above by the Department is for identification purposes only.

The use of the STI Chem-Clav Series 2000 unit for the treatment of regulated medical waste is approved in Alabama under the following conditions:

1. The chemical agent (sodium hypochlorite) must be used according to manufacturer's instructions and specifications.

2. Any free liquids remaining after use must be properly managed.

3. This equipment is not approved for Chemotherapy Waste.

4. This approval is contingent upon the equipment being operated within the manufacturer's design specifications and operating parameters.

5. This approval is granted for the specific model listed above. Any modifications to the system may require an additional approval and may involve further efficacy testing.

6. The equipment must render sharps, recognizable body parts and medical labeling unrecognizable as determined by the disposal facility accepting the waste and the Department if disposal is to take place in Alabama.

7. Anyone utilizing this equipment to treat regulated medical waste in Alabama shall obtain a valid permit to operate a medical waste treatment facility from this office.

By issuance of this letter, the Department is not providing any endorsement, expressing or implying any warranty, or making any type of recommendation on its use.

This approval is valid until Alabama's regulations have been modified to require another approval or the process is later determined to be ineffective. If you have any questions, please contact the Solid Waste Branch at (334) 271-7761.

Sincerely,

Wm. Gerald Hardy, Chief
Land Division

WGH/GLM/SWaste for glm (Chem-Clav)

C: Mr. Charles Crochet
AM 3CI

File: Med/W - Alternate Treatment Technology
Sterile Technologies Industries, Inc.
Chem-Clav

BioSAFE Engineering

To whom it may concern;

The STI Chem-Clav Series 2000, a regulated medical waste treatment system, is manufactured and marketed by Sterile Technologies, a BioSAFE brand. The equipment has not been modified since its approval by ADEM in December 1998. Specifically, the unit primarily utilizes sodium hypochlorite and low-pressure steam to treat regulated medical waste. The mode of treatment and method of efficacy testing have not changed since the issuance of the letter authorizing the STI Chem-Clav Series 2000 as an alternative treatment technology.

If you have any questions, please contact us at dnelsen@biosafeeng.com.

Sincerely,

BioSAFE Engineering
Roland Kallechy
Director of Operations
5750 W. 80th St.
Indianapolis, IN 46278
Ph: (317)858-8099 – Ext 203
Fax: (317)858-8202
rkallechy@biosafeengineering.com

ANALYTICAL SERVICES, INC. (ASI)
Microbiological Testing, Research and Consulting

130 Allen Brook Ln., PO Box 515, Williston, VT 05495 USA
1.800.723.4432 / 802.878.5138 Fax: 802.878.6765
www.analyticalservices.com

28 February 2005

Randy McKee
Sterile Technology Industries, Inc.
2910-D Fortune Circle West
Indianapolis, IN 46241

Subject: Letter of Transmittal – ASI Report No. 2005-0128-004

Dear Randy,

Enclosed herein please find a analytical Services, Inc.'s (ASI) report regarding the medical waste treatment validation testing that was performed by Analytical Services, Inc. (ASI) on your behalf during January 2005. This report includes a brief description of the project, results and a discussion section. Documentation from Dr. Ira Salkin, who served as ASI's on-site representative during the trials, is appended.

We appreciate your decision to utilize ASI as a microbiological laboratory resource and look forward to furthering our business relationship. If you have any questions, please contact me at anytime.

Sincerely,

ANALYTICAL SERVICES, INC. (ASI)

Paul S. Warden
Vice President

Project Overview

ASI was contracted to provide laboratory support services for medical waste treatment validation trials to be performed at two sites, Muhlenburg Regional Medical Center (Plainfield, NJ) and LabCorp (Raritan, NJ).

ASI provided bacterial stock propagation, sample preparation and seeding, shipping, on-site observation of waste treatment trials, and microbiological analyses. ASI contracted Dr. Ira Salkin of Information From Science, LLC (West Sand Lake, NY) to serve as our on-site representative during the trials. As the on-site microbiologist, Dr. Salkin handled the samples before and after treatment, recorded on-site data and observations and shipped the samples to ASI for analysis. Upon receipt of treated and control samples; ASI processed them in accordance with the previously approved protocols.

Methods

Mycobacterium terrae (ATCC 15755) was propagated by ASI and suspensions prepared in accordance with our standard procedure. Suspensions of *B. atrophaeus* (ATCC 9372) spores were procured from Sterilator Company, Inc. (Cuba, NY) for use in this study. The *Bacillus* suspensions were enumerated at ASI concurrently with inoculation of the samples (as described below) that were shipped by overnight delivery to the second test site. STI provided treated, shredded medical waste and glassine envelopes (Glassine USA, Springfield, OR).

Muhlenburg Sample Preparation – Fifteen (15) samples were prepared as 10-gram medical waste aliquots in individual glassine envelopes, each seeded with 1.0 mL of *Mycobacterium* stock (which had a concentration of 8.0×10^8 CFU/mL). These samples were shipped to the Muhlenburg site via FedEx Priority delivery.

LabCorp Sample Preparation - A second set of 15 samples were prepared as 10-gram medical waste aliquots in individual glassine envelopes, each seeded with 1.0 mL of *Mycobacterium* stock (which had a concentration of 8.0×10^8 CFU/mL). Another set of 15 samples were prepared as 10-g medical waste aliquots in individual glassine envelopes, each seeded with 1.0 mL of *Bacillus* spore suspension (2.0×10^8 CFU/mL). These samples were packaged and shipped to the LabCorp site via FedEx Priority delivery.

Samples were received on-site and the medical waste treatment trials were performed as proscribed in the previously approved protocols. A report for each site, prepared by Dr. Salkin, is enclosed.

Samples were received at ASI, inspected and judged in good condition. All samples were eluted in 100 mL TSB in 250 mL flasks, which were put in an incubator shaker for 2 minutes at 200 RPM and subsequently processed in accordance with the approved protocols. While the protocols do not require negative laboratory control samples, these were prepared and processed concurrently with the trial samples as part of ASI's standard procedures. All sample manipulations and plate examinations were performed in biosafety hoods using aseptic techniques.

Results

The results are displayed in Tables 1 – 3.

Table 1. Summary of *Mycobacterium* results from STI medical waste validation trial conducted at Muhlenberg Medical Center (Plainfield, NJ) on 26 Jan 2005 (Incubation: 21d, 35±0.5°C).

ASI Sample No.	Description [A]	Result (CFU/g) [B]	Log_{10} Value	Log Reduction [C]
2005-0127-004	TS-1	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-005	TS-2	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-006	TS-3	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-007	TS-4	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-008	TS-5	3.3×10^0	0.5	6.6
2005-0127-009	TS-6	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-010	TS-7	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-011	TS-8	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-012	TS-9	$<3.3 \times 10^0$	<0.5	>6.6
2005-0127-013	UC-1	2.3×10^7	7.3	Mean $UC_{Log10} = 7.1$
2005-0127-014	UC-2	9.7×10^6	6.9	
2005-0127-015	UC-3	1.6×10^7	7.2	
2005-0127-016	FC-1	3.0×10^7	7.4	Mean $FC_{log10} = 7.3$
2005-0127-017	FC-2	4.8×10^7	7.6	
2005-0127-018	FC-3	8.3×10^6	6.9	

[A] Note: TS = Treated Sample UC = Untreated Control FC = Field Control

[B] Method: Individual samples were prepared by filling 15 glassine envelopes with 10 gm of medical waste each, and seeding with 1.0 mL of *Mycobacterium* suspension. Samples were shipped to the test site via FedEx and returned similarly after the field trial. Upon receipt at ASI, each sample was eluted in TSB and serial dilutions plated as per the referenced protocol.

[C] Log Reduction values calculated as LRV = (Log_{10} Mean Untreated Control) – (Log_{10} Treated Sample).

NOTE: As recommended, 3 Lab Control samples (seeded, not shipped) were prepared, held at ASI and analyzed with the test samples. The mean recovered concentration of *M. terrae* was 4.9×10^7 CFU/g (7.6 Log), similar to the Untreated and Field Control results. Negative control samples (processed concurrently with experimental samples) were all negative.

Table 2. Summary of *Bacillus* results from STI medical waste validation trial conducted at LabCorp (Raritan, NJ) on 27 January 2005 (Incubation: 7 days, 35±0.5°C).

ASI Sample No.	Description [A]	Result (CFU/g) [B]	Log_{10} Value	Log Reduction [C]
2005-0128-004	TS-1	6.8×10^2	2.8	4.4
2005-0128-005	TS-2	2.1×10^2	2.3	4.9
2005-0128-006	TS-3	7.7×10^1	1.9	5.3
2005-0128-007	TS-4	3.0×10^1	1.5	5.7
2005-0128-008	TS-5	4.7×10^1	1.7	5.5
2005-0128-009	TS-6	1.3×10^1	1.1	6.1
2005-0128-010	TS-7	3.0×10^1	1.5	5.7
2005-0128-011	TS-8	$<3.0 \times 10^0$ [D]	<0.5	>6.7
2005-0128-012	TS-9	1.3×10^1	1.1	6.1
2005-0128-022	UC-1	1.7×10^7	7.2	Mean $UC_{Log10} = 7.2$
2005-0128-023	UC-2	1.6×10^7	7.2	
2005-0128-024	UC-3	2.2×10^7	7.3	
2005-0128-028	FC-1	2.7×10^7	7.4	Mean $FC_{log10} = 7.2$
2005-0128-029	FC-2	1.6×10^7	7.2	
2005-0128-030	FC-3	1.4×10^7	7.1	

[A] Note: TS = Treated Sample UC = Untreated Control FC = Field Control

[B] Method: Individual samples were prepared by filling 15 glassine envelopes with 10 gm of medical waste each, and seeding with 1.0 mL of *Bacillus* suspension. Samples were shipped to the test site via FedEx and returned similarly after the field trial. Upon receipt at ASI, each sample was eluted in TSB and serial dilutions plated as per the referenced protocol.

[C] Log Reduction values calculated as LRV = (Log_{10} Mean Untreated Control) – (Log_{10} Treated Sample).

[D] All 3 plates (1 mL each) were negative for *Bacillus* after 7 days of incubation.

NOTE: As recommended, 3 Lab Control samples (seeded, not shipped) were prepared, held at ASI and analyzed with the test samples. The mean recovered concentration of *B. atrophaeus* was 1.56×10^7 CFU/g (7.2 Log), similar to the Untreated and Field Control results. Negative control samples (processed concurrently with experimental samples) were all negative.

Table 3. Summary of *Mycobacterium* results from STI medical waste validation trial conducted at LabCorp (Raritan, NJ) on 27 January 2005 (Incubation: 21 days, 35±0.5°C).

ASI Sample No.	Description [A]	Result (CFU/g) [B]	Log_{10} Value	Log Reduction [C]
2005-0128-013	TS-1	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-014	TS-2	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-015	TS-3	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-016	TS-4	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-017	TS-5	3.3×10^0	0.5	7.1
2005-0128-018	TS-6	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-019	TS-7	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-020	TS-8	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-021	TS-9	$<3.3 \times 10^0$	<0.5	>7.1
2005-0128-025	UC-1	3.9×10^7	7.5	
2005-0128-026	UC-2	4.0×10^7	7.6	Mean $UC_{Log10} = 7.6$
2005-0128-027	UC-3	4.3×10^7	7.6	
2005-0128-031	FC-1	5.5×10^7	7.7	
2005-0128-032	FC-2	5.0×10^7	7.6	Mean $FC_{log10} = 7.6$
2005-0128-033	FC-3	5.7×10^7	7.7	

[A] Note: TS = Treated Sample UC = Untreated Control FC = Field Control

[B] Method: Individual samples were prepared by filling 15 glassine envelopes with 10 gm of medical waste each, and seeding with 1.0 mL of *Mycobacterium* suspension. Samples were shipped to the test site via FedEx and returned similarly after the field trial. Upon receipt at ASI, each sample was eluted in TSB and serial dilutions plated as per the referenced protocol.

[C] Log Reduction values calculated as LRV = (Log_{10} Mean Untreated Control) – (Log_{10} Treated Sample).

Discussion

The data demonstrate an average 6.8 log reduction in *Mycobacterium terrae*, in all samples due to treatment (Muhlenberg 6.6 log and LabCorp 7.1 log) This statement is supported by comparing the treated sample results to the untreated control samples for each of the respective sites.

The *Bacillus atrophaeus* spore data from LabCorp Indicate an average kill of 5.6 log (range: 4.4 to >6.7 log). The Untreated Control. Field Control and Lab Control samples had very consistent results, averaging 7. 2 log (range 7.1 - 7.8 log).

The *Bacillus* results differ from what was observed in December 2004 testing (>6.6 log reduction). At that time, discussion centered upon whether the interruption (overnight refrigeration) in the specified 7 day incubation period might have prevented injured *Bacillus* spores from recovering, and consequently the test was repeated. However, recovery of injured microorganisms after prolonged incubation was not the cause of the positive *Bacillus* results in this trial, as *Bacillus* colonies were first observed after only 48 hours of incubation.

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EFFICACY TESTING OF STI MEDICAL WASTE TREATMENT SYSTEM

MUHLENBURG MEDICAL CENTER

JANUARY 26, 2005

The following tests were conducted at Muhlenburg Medical Center as per the protocols approved by the New Jersey Department of Health and Senior Services:

1. Field Control Samples

Three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Mycobacterium terrae* (ATCC 15755) as received from Analytical Services, Inc. (Williston, VT) were immediate placed under refrigeration, without further processing, to be held for return to Analytical Services.

2. Untreated Control Samples

Three (3) samples containing mycobacterial spiked waste, identical in composition to the field controls, were inserted into carriers, i.e., "eggs" and processed through the STI treatment system, **WITHOUT** the use of the heat generated by steam and substituting water for the use of bleach. The duration of exposure was similar to that when the system is used to treat medical waste. The temperatures of the STI during this portion of the testing were 70°F for the "lower clave" and 105°F for the "upper clave". When the eggs were captured at the end of their passage through the system, the samples were removed, immediately placed under refrigeration until they were transported to Analytical Services.

3. Treated Samples

Three (3) samples containing mycobacterial spiked waste, identical in composition to the field and untreated controls, were inserted into two "eggs" and processed through the STI treatment system, along with routine medical waste from the facility, under normal operating treatment parameters, but substituting water for the use of bleach. When the eggs were captured at the end of their passage through the system, the samples were removed, immediately placed under refrigeration until they were transported to Analytical Services.

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Test Run # 3

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 2:40 pm – Eggs V (samples 7 & 8) and VI (sample 9)
- Retrieval times – Egg V = 4:37 pm.; Egg VI= 4:50 pm
- Residence times – Egg V = 1 hr/57 min; Egg IV = 2 hr/10 min
- Temperature recorded
  - Time 0 – 208°F – lower clave; 205°F – upper clave
  - Time 15 min – 210°F – lower clave; 205°F – upper clave
  - Time 30 min – 208°F – lower clave; 206°F – upper clave
  - Time 45 min – 208°F–lower clave; 206°F – upper clave
  - Time 60 min – 208°F – lower clave; 206°F – upper clave
  - Time 75 min – 210°F – lower clave; 210°F – upper clave
  - Time 90 min – 212°F – lower clave; 215°F – upper clave
  - Time 105 min – 212°F – lower clave; 213°F – upper clave
  - Time 120 min – 210°F – lower clave; 211°F – upper clave

Average duration of exposure – all test runs = 2 hr/03 min
Average temperature of exposure – all test runs = 209.1°F – lower clave; 207.5°F – upper clave

4. Return of Samples

At the conclusion of all testing, samples were removed from refrigeration, packaged in an insulated container with frozen cold packs and FedExed, overnight, to Analytical Services where they were received by 10:30 am the following day.

Submitted

Ira F. Salkin, Ph.D., F(AAM)
For Analytical Services

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EFFICACY TESTING OF STI MEDICAL WASTE TREATMENT SYSTEM

LABCORP LABORATORIES

JANUARY 27, 2005

The following tests were conducted at LabCorp Laboratories as per the protocols approved by the New Jersey Department of Health and Senior Services:

1. Field Control Samples

Three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Mycobacterium terrae* (ATCC 15755) and three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Bacillus atrophaeus* (ATCC 9372) as received from Analytical Services, Inc. (Willlston, VT) were immediate placed under refrigeration, without further processing, to be held for return to Analytical Services.

2. Untreated Control Samples

Three (3) samples containing mycobacterial spiked waste and three (3) samples containing bacterial spore spiked waste, identical in composition to the field controls, were inserted into carriers, i.e., "eggs" and processed through the STI treatment system, **WITHOUT** the use of the heat generated by steam and substituting water for the use of bleach. The duration of exposure was similar to that when the system is used to treat medical waste. The temperatures of the STI during this portion of the testing were 95°F for the "lower clave" and 98°F for the "upper clave". When the eggs were captured at the end of their passage through the system, the samples were removed and immediately placed under refrigeration until they were transported to Analytical Services.

3. Treated Samples

Three (3) samples containing mycobacterial spiked waste and three (3) samples containing bacterial spore spiked waste, identical in composition to the field and untreated controls, were inserted into separate "eggs" and processed through the STI treatment system, along with routine medical waste from the facility, under normal

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operating treatment parameters, but substituting water for the use of bleach as a deodorizing agent. When the eggs were captured at the end of their passage through the system, the samples were removed and immediately placed under refrigeration until they were transported to Analytical Services.

The following are the descriptions of each of the three test runs, each involving two (2) eggs, one containing the three (3) mycobacterial samples and the second, the three (3) bacterial spore samples:

Test Run # 1

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:30 am – Eggs I and II
- Retrieval times – Egg I & Egg II = 12:07 pm
- Residence times – Egg I & Egg II = 1 hr/37 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 217-218°F – upper clave
  - Time 15 min – 215-216°F – lower clave; 216 -217°F – upper clave
  - Time 30 min - 215-216°F – lower clave; 215-216°F – upper clave
  - Time 45 min - 215-216°F – lower clave; 215-216°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216 -217°F – upper clave

Test Run # 2

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:35 am – Eggs III and IV
- Retrieval times – Egg III (mycobacteria) =12:17 pm and Egg IV (*Bacillus)* = 1:08 pm
- Residence times – Egg III = 1 hr/42 min and Egg IV = 2 hr/33 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 217-218°F – upper clave
  - Time 15 min – 215-216°F – lower clave; 216 -217°F – upper clave
  - Time 30 min - 215-216°F – lower clave; 215-216°F – upper clave
  - Time 45 min - 215-216°F – lower clave; 215-216°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216 -217°F – upper clave

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Test Run # 3

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:40 am – Eggs V and VI
- Retrieval times – Eggs V & VI = 12:25 pm
- Residence times – Eggs V & VI = 1 hr/45 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 216 -217°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216F-217°F – upper clave

Average duration of exposure – all test runs = 1 hr/56 min
Average temperature of exposure – all test runs = 214 - 215°F – lower clave; 216 – 217°F – upper clave

It should be noted that one sample containing waste spiked with mycobacteria and one spiked with bacterial spores were found to have opened during their transport within there respective eggs through the steam auger of the STI. However, careful retrieval of the glassine envelopes when removed from the eggs permitted the recovery of all of the contents within the individual envelopes and their transfer to Analytical Services as separate test samples.

4. Return of Samples

At the conclusion of all testing, samples were removed from refrigeration, packaged in an insulated container with frozen cold packs and FedExed, overnight to Analytical Services where they were received by 10:30 am the following day.

Submitted

Ira F. Salkin, Ph.D., F(AAM)
For Analytical Services

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EFFICACY TESTING OF STI MEDICAL WASTE TREATMENT SYSTEM

MUHLENBURG MEDICAL CENTER

JANUARY 26, 2005

The following tests were conducted at Muhlenburg Medical Center as per the protocols approved by the New Jersey Department of Health and Senior Services:

1. Field Control Samples

Three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Mycobacterium terrae* (ATCC 15755) as received from Analytical Services, Inc. (Williston, VT) were immediate placed under refrigeration, without further processing, to be held for return to Analytical Services.

2. Untreated Control Samples

Three (3) samples containing mycobacterial spiked waste, identical in composition to the field controls, were inserted into carriers, i.e., "eggs" and processed through the STI treatment system, **WITHOUT** the use of the heat generated by steam and substituting water for the use of bleach. The duration of exposure was similar to that when the system is used to treat medical waste. The temperatures of the STI during this portion of the testing were 70°F for the "lower clave" and 105°F for the "upper clave". When the eggs were captured at the end of their passage through the system, the samples were removed, immediately placed under refrigeration until they were transported to Analytical Services.

3. Treated Samples

Three (3) samples containing mycobacterial spiked waste, identical in composition to the field and untreated controls, were inserted into two "eggs" and processed through the STI treatment system, along with routine medical waste from the facility, under normal operating treatment parameters, but substituting water for the use of bleach. When the eggs were captured at the end of their passage through the system, the samples were removed, immediately placed under refrigeration until they were transported to Analytical Services.

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The following are the descriptions of each of the three test runs, each involving two (2) eggs containing the three (3) mycobacterial samples:

Test Run # 1

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 2:15 pm – Eggs I (samples 1 & 2) and II (sample 3)
- Retrieval times – Egg I = 4:12 pm.; Egg II = 4:08 pm
- Residence times – Egg I = 1 hr/57 min; Egg II 1 hr/53 min
- Temperature recorded
  - Time 0 – 207°F – lower clave; 206°F – upper clave
  - Time 15 min – 207°F – lower clave; 205°F – upper clave
  - Time 30 min – 208°F – lower clave; 205°F – upper clave
  - Time 45 min – 209°F–lower clave; 205°F – upper clave
  - Time 60 min – 208°F – lower clave; 206°F – upper clave
  - Time 75 min – 208°F – lower clave; 205°F – upper clave
  - Time 90 min – 209°F – lower clave; 206°F – upper clave
  - Time 105 min – 210°F – lower clave; 211°F – upper clave

Test Run # 2

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 2:30 pm – Eggs III (samples 4 & 5) and IV (sample 6)
- Retrieval times – Egg III = 4:20 pm.; Egg IV= 4:41 pm
- Residence times – Egg III = 1 hr/50 min; Egg IV = 2 hr/11 min
- Temperature recorded
  - Time 0 – 207°F – lower clave; 205°F – upper clave
  - Time 15 min – 208°F – lower clave; 205°F – upper clave
  - Time 30 min – 209°F – lower clave; 205°F – upper clave
  - Time 45 min – 208°F–lower clave; 206°F – upper clave
  - Time 60 min – 208°F – lower clave; 205°F – upper clave
  - Time 75 min – 209°F – lower clave; 206°F – upper clave
  - Time 90 min – 210°F – lower clave; 210°F – upper clave
  - Time 105 min – 214°F – lower clave; 214°F – upper clave
  - Time 120 min – 211°F – lower clave; 211°F – upper clave
  - Time 135 min – 212°F – lower clave; 213°F – upper clave

INFORMATION FROM SCIENCE LLC
P. O. BOX 408
WEST SAND LAKE, NEW YORK 12196
VOICE/FAX – 518-674-1713
E-MAIL – IRASALKIN@AOL.COM

Test Run # 3

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 2:40 pm – Eggs V (samples 7 & 8) and VI (sample 9)
- Retrieval times – Egg V = 4:37 pm.; Egg VI= 4:50 pm
- Residence times – Egg V = 1 hr/57 min; Egg IV = 2 hr/10 min
- Temperature recorded
  - Time 0 – 208°F – lower clave; 205°F – upper clave
  - Time 15 min – 210°F – lower clave; 205°F – upper clave
  - Time 30 min – 208°F – lower clave; 206°F – upper clave
  - Time 45 min – 208°F–lower clave; 206°F – upper clave
  - Time 60 min – 208°F – lower clave; 206°F – upper clave
  - Time 75 min – 210°F – lower clave; 210°F – upper clave
  - Time 90 min – 212°F – lower clave; 215°F – upper clave
  - Time 105 min – 212°F – lower clave; 213°F – upper clave
  - Time 120 min – 210°F – lower clave; 211°F – upper clave

Average duration of exposure – all test runs = 2 hr/03 min
Average temperature of exposure – all test runs = 209.1°F – lower clave; 207.5°F – upper clave

4. Return of Samples

At the conclusion of all testing, samples were removed from refrigeration, packaged in an insulated container with frozen cold packs and FedExed, overnight, to Analytical Services where they were received by 10:30 am the following day.

Submitted

Ira F. Salkin, Ph.D., F(AAM)
For Analytical Services

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EFFICACY TESTING OF STI MEDICAL WASTE TREATMENT SYSTEM

LABCORP LABORATORIES

JANUARY 27, 2005

The following tests were conducted at LabCorp Laboratories as per the protocols approved by the New Jersey Department of Health and Senior Services:

1. Field Control Samples

Three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Mycobacterium terrae* (ATCC 15755) and three (3)-ten (10) gm samples of autoclaved, shredded medical waste, each spiked with one (1) ml of a suspension containing 10^8 cfu/ml of *Bacillus atrophaeus* (ATCC 9372) as received from Analytical Services, Inc. (Williston, VT) were immediate placed under refrigeration, without further processing, to be held for return to Analytical Services.

2. Untreated Control Samples

Three (3) samples containing mycobacterial spiked waste and three (3) samples containing bacterial spore spiked waste, identical in composition to the field controls, were inserted into carriers, i.e., "eggs" and processed through the STI treatment system, **WITHOUT** the use of the heat generated by steam and substituting water for the use of bleach. The duration of exposure was similar to that when the system is used to treat medical waste. The temperatures of the STI during this portion of the testing were 95°F for the "lower clave" and 98°F for the "upper clave". When the eggs were captured at the end of their passage through the system, the samples were removed and immediately placed under refrigeration until they were transported to Analytical Services.

3. Treated Samples

Three (3) samples containing mycobacterial spiked waste and three (3) samples containing bacterial spore spiked waste, identical in composition to the field and untreated controls, were inserted into separate "eggs" and processed through the STI treatment system, along with routine medical waste from the facility, under normal

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operating treatment parameters, but substituting water for the use of bleach as a deodorizing agent. When the eggs were captured at the end of their passage through the system, the samples were removed and immediately placed under refrigeration until they were transported to Analytical Services.

The following are the descriptions of each of the three test runs, each involving two (2) eggs, one containing the three (3) mycobacterial samples and the second, the three (3) bacterial spore samples:

Test Run # 1

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:30 am – Eggs I and II
- Retrieval times – Egg I & Egg II = 12:07 pm
- Residence times – Egg I & Egg II = 1 hr/37 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 217-218°F – upper clave
  - Time 15 min – 215-216°F – lower clave; 216 -217°F – upper clave
  - Time 30 min - 215-216°F – lower clave; 215-216°F – upper clave
  - Time 45 min - 215-216°F – lower clave; 215-216°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216 -217°F – upper clave

Test Run # 2

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:35 am – Eggs III and IV
- Retrieval times – Egg III (mycobacteria) =12:17 pm and Egg IV (*Bacillus)* = 1:08 pm
- Residence times – Egg III = 1 hr/42 min and Egg IV = 2 hr/33 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 217-218°F – upper clave
  - Time 15 min – 215-216°F – lower clave; 216 -217°F – upper clave
  - Time 30 min - 215-216°F – lower clave; 215-216°F – upper clave
  - Time 45 min - 215-216°F – lower clave; 215-216°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216 -217°F – upper clave

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Test Run # 3

- Responsible test manager – Ira F. Salkin, Ph.D., F(AAM)
- Insertion time – 10:40 am – Eggs V and VI
- Retrieval times – Eggs V & VI = 12:25 pm
- Residence times – Eggs V & VI = 1 hr/45 min
- Temperature recorded
  - Time 0 – 214-215°F – lower clave; 216 -217°F – upper clave
  - All subsequently temperature readings remained constant at 214-215°F – lower clave; 216F-217°F – upper clave

Average duration of exposure – all test runs = 1 hr/56 min
Average temperature of exposure – all test runs = 214 - 215°F – lower clave; 216 – 217°F – upper clave

It should be noted that one sample containing waste spiked with mycobacteria and one spiked with bacterial spores were found to have opened during their transport within there respective eggs through the steam auger of the STI. However, careful retrieval of the glassine envelopes when removed from the eggs permitted the recovery of all of the contents within the individual envelopes and their transfer to Analytical Services as separate test samples.

4. Return of Samples

At the conclusion of all testing, samples were removed from refrigeration, packaged in an insulated container with frozen cold packs and FedExed, overnight to Analytical Services where they were received by 10:30 am the following day.

Submitted

Ira F. Salkin, Ph.D., F(AAM)
For Analytical Services

City Planning and Zoning

2020 Valleydale Rd.
Hoover, AL 35244
Phone (205) 444-7648

FRANK V. BROCATO
Mayor

MAC MARTIN
City Planner

March 8, 2024

BioLife Plasma Services, LP
ATTN: Trysh Pierce
2197 Parkway Lake Drive
Hoover, AL 35244

Emailed to patricia.pierce@takeda.com

RE: BioLife Medical Waste Disposal

Hello.

This letter is a response to the inquiry made concerning the BioLife Testing Laboratory at the subject address and the ability to use the site for steam sterilization waste processing. The City considers the BioLife Testing Laboratory with the STI300 steam sterilization waste facility produced by BioSafe Engineering, which only processes waste generated on the site, as a permitted use within the industrial zone (PI – Planned Industrial) within which it is located.

Please let me know if there is anything else we can do for you!

Thank you!

Mac W. Martin, Jr., AICP
City Planner