Permit No.	Scan Date	DIN
3615-TP-2011	**October 18, 2012**	**17475**

RECEIVED
October 15, 2012
Solid Waste Section
Asheville Regional Office

Assured Waste Solutions
PO Box 536, Gastonia, NC 28053
www.assuredwastesolutions.com
704-865-7550

October 15, 2012

North Carolina DENR
Division of Waste Management
2090 US Highway 70
Swannanoa, NC 28778

Attn: Larry Frost

Dear Larry:

This is to inform the Department that MedWaste Solutions, LLC (NC Permit #3615) is changing the company name to Assured Waste Solutions, LLC. This is a name change only with no changes in company structure or ownership.

In this regard, I have attached a revised Operation Plan to reflect the name change and update it for some additions to the plant that we have discussed since the original issuing of our permit. The biggest change to our company is the addition of us handling pharmaceuticals as a reverse distributor. This does not change anything concerning our processing of medical waste as the pharmaceuticals are handled separately and under a DEA permit. I have attached our Operating Plan for the pharmaceutical division, called Assured Pharmaceuticals, as Exhibit 2 to our Operating Plan.

This morning I will be picking up the documents to sign to redo the financial assurance Letter of Credit with the bank and will send a copy to you later after I get the appropriate signatures. I will also send a revised plant drawing in that packet along with a hard copy of the revised Operating Plan.

Please let me know if you need any additional information as we make this name change.

Sincerely,

Gerry Moore, Plant Manager

Assured Waste Solutions, LLC
Medical Waste Treatment Facility
Gastonia, North Carolina
NC Permit #3615

OPERATION PLAN

October 15, 2012

1.0 INTRODUCTION

Assured Waste Solutions, LLC operates a medical waste treatment facility located at 148 Boxwood Lane, Gastonia, NC. The site, consisting of a 10,000 square foot building on approximately two (2) acres is properly zoned with sanitary sewer and natural gas service. The site is properly suited for medical waste treatment operations, transfer of medical waste for appropriate treatment off site, and transportation and storage of untreated and treated medical waste. The facility can house four (4) steam sterilization (autoclave) units. Treated waste is transferred into a container prior to being transported to a permitted Sub-Title D landfill under contract to Waste Management, Inc. The operating parameters for waste treatment are detailed in this Operating Plan, with applicable requirements set forth in the North Carolina GS 130A-294, Solid Waste Management Program and including 15A NCAC 13B. The facility also does reverse distribution and destruction of pharmaceuticals under guidelines of the EPA and DEA.

2.0 FACILITY IDENTIFICATION

Assured Waste Solutions, LLC
148 Boxwood Lane
Gastonia, NC. 28054

3.0 OPERATIONS

The facility is operated in accordance with rules and regulations set forth by the Division of Waste Management, North Carolina GS 130A-294, Solid Waste Management Program, 15A NCAC 13B and the City of Gastonia, NC. The manufacture's Operating Manuals are kept on file at the plant office. All employees, based on job description, shall receive training as to the contents of the manual, safety procedures and practices, operation, maintenance, and servicing of the equipment. Assured Waste Solutions accepts prepackaged boxes, reusable and disposable containers of various sizes containing medical waste and sharps waste from generators and transporters. The waste is treated by means of steam sterilization equipment after which it is disposed of in a permitted Sub-Title D landfill. Wastes requiring incineration will be transferred to a permitted incinerator capable of treating by pass waste that includes all waste material that is not treatable in the autoclave sterilization process, i.e. pharmaceuticals, pathological (human and animal), liquids, etc. as governed by 15A NCAC 13B. The facility also operates under EPA and DEA permits to transport and process pharmaceuticals for reverse distribution and destruction (See attached Pharmaceuticals Operation Plan, Exhibit 2). This section summarizes the routine operating procedures for the safe and effective management of the waste. The section includes procedures and policies for the following:

1. Equipment operation and maintenance
2. Onsite waste flow
3. Unloading procedures
4. Sorting/inspection/recording procedures
5. Hours of operation
6. Access control
7. Time and capacity limits

3.1 EQUIPMENT OPERATION AND MAINTENANCE

3.1A General Operations

Waste is transported to the treatment facility from generators, by way of Assured Waste Solutions drivers or licensed transporters with whom Assured Waste Solutions contracts treatment services. Waste is received at the facility in corrugated boxes or reusable and other disposable containers where they are offloaded from vehicles at the dock doors. Personnel using hand trucks, forklifts, and conveyors, transfer the waste to a scale/barcode scanning station, where the customer information and container weight is recorded. Once scanned and weighed, the waste is loaded into treatment carts, staged and treated in the autoclave. After treatment the waste is transferred to a waste container for transport to a permitted disposal landfill. Any waste requiring incineration will be transferred to another properly licensed and permitted incinerator or treatment facility. Incineration waste is primarily noticed by visual inspection of the red bags as they are transferred into the treatment carts and by an abnormal weight situation. The main objective is to work with and train our customers to properly segregate and label the various waste streams. Proper handling at the source will minimize the handling of waste materials at the treatment facility.

The autoclave control system is a comprehensive data collection, display and retention which is operator friendly while providing detailed electronic and hard copy management of data for regulatory purposes and for demonstrating treatment efficacy and securing the operating data for a period of seven (7) years.

To respond to the concerns relative to the presence of radioactive materials in the waste loads, radioactivity detectors are mounted over each dock receiving door which gives an alarm upon the detection of radioactive substances in the load. The radioactive waste will be located and returned to the generator or picked up by an approved transporter.

There are no added chemicals introduced into the steam sterilization process. A built in cool down cycle avoids handling of hot carts, thus preventing exposure to potential injury.

3.1B Detailed Operations

3.1B(1) Service

Assured Waste Solutions provides collection and/or treatment services to the healthcare industry in this region. The service usually includes providing containers and other necessary supplies for proper packaging of the waste materials along with barcode labels for transport and tracking.

Proper packaging includes using only approved red bags and cardboard boxes, tape, and labels. Boxes that are not packaged properly will not be picked up including weighing over 50 pounds, boxes that are crushed, torn or distorted in any way, label not attached (name and address correct), or not completely taped shut on the top and bottom. Any nonconforming boxes must be repackaged before picked up for transport.

3.1B(2) Medical Waste Transport

Medical waste will be transported in trucks by employees of Assured Waste Solutions, contract drivers for Assured Waste Solutions, and other waste transporters. Medical waste is shipped to the facility in approved corrugated boxes, reusable containers, or other disposable containers. Assured Waste Solutions will not transport, or accept for transport, waste that is not properly packaged or classified in accordance with 15A NCAC 13B section .1204.

Assured Waste Solutions shall also maintain compliance with the requirements of section 15A NCAC 13B .1205 which includes:

- Transporters shall not accept waste that is improperly packaged.
- Regulated medical waste shall be transported in a manner that prevents leakage of the contents of the package.
- The integrity of the package shall be maintained at all times.
- The labeling and marking of the package shall be maintained at all times.
- All loads containing regulated medical waste shall be covered during transportation.
- The universal biohazard symbol shall be displayed on all transportation vehicles, in accordance with the US DOT Standards and 49CFR 172 Subpart F.
- Regulated medical waste shall be delivered to a permitted storage of treatment facility within seven (7) calendar days of the date of shipment from the generator.
- Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for regulated medical waste that will not be delivered for treatment within seven (7) calendar days.
- A contingency plan shall be prepared and maintained in each vehicle used in the transporting of regulated medical waste. The operator of each vehicle shall be knowledgeable of the plan.
- Vehicles used for the transportation of regulated medical waste shall be thoroughly cleaned and disinfected with a mycobacteriocidal disinfectant before being used for any other purpose and in the event of leakage from packages.
- While transporting regulated medical waste, vehicles are prohibited from transporting any material other than solid waste and supplies related to the handling of medical waste.

3.1B(3) Container Unloading and Handling

The waste containers are offloaded at the dock by hand truck, forklift, conveyor or rolled off (some containers are equipped with wheels) by plant employees. The dock area will remain clear of debris and forklift accessible. Entrance into the plant from the dock is through two roll up doors, one being 8’ wide x 12’ high, and the other 12’ wide x 12’ high.

Packages of waste shall remain intact from the generator's site during transport and to time of processing in the staging area. There shall be no recycling efforts or intentional removal of waste from the red bags or sharps containers prior to the waste being treated. Packaging of waste is handled in a manner that does not impair the integrity of the packaging. Containers of waste shall not be compacted before transfer.

All reusable waste containers shall be constructed of smooth and easily cleanable materials that are impervious to liquids and capable of being readily maintained in sanitary condition.

3.1B(4) Unacceptable Waste

Properly classified waste materials, which are received at the facility, but cannot be processed by steam sterilization, are segregated and staged for further transport to an alternate facility. Unacceptable waste received is returned to the generator, as soon as practical, or is transferred to an appropriate disposal facility. Shipping documents are utilized to track this material to the proper treatment and disposal facility. No waste will be accepted that does not meet the packaging requirements of 15A NCAC 13B .1204.

3.1B(5) Treatment Cart Loading (Manual and Hydraulic Dumpers)

After waste containers have been scanned and weighed, they are conveyed to a dumping platform or hydraulic tipper/dumper. Disposable contents and/or the contents of the reusable containers are then dumped into the plastic lined treatment carts.

After dumping, the reusable containers are conveyed to a container washing area where they are cleaned with hot water and an approved disinfectant. The dumping process is repeated until the treatment carts are full or until they have the proper weight in them for loading into the autoclave.

3.1B(6) Medical Waste Weighing

Waste received at the facility is unloaded and tracked by scanning a customer installed barcode, provided by Assured Waste Solutions, as it passes over a scale. This provides the information for regulatory and billing purposes. Also, the autoclave contains a scale to weigh each load before it is rolled into the chamber.

3.1B(7) Container Disinfection

After the reusable containers are emptied, they are conveyed to a hot water cleaning station where they are disinfected and washed with a high-pressure spray. When the cleaning operation is completed, the containers are staged to dry. Containers are then either moved to a storage area or loaded onto trucks for delivery to a generating facility for the collection of waste.

3.1B(8) Loading and Unloading Autoclave

Once the treatment carts are filled with untreated medical waste, the carts are conveyed to a staging position. Treatment carts are then loaded into the autoclave.

Unloading treated carts of waste material is conducted the same way, after which, they are staged to be emptied into the disposal container. The carts are emptied into the disposal container by use of a forklift or other hydraulic means. Once emptied, the treatment carts are relined and available again for refill with untreated medical waste. If a cart contains any residue after dumping it will be taken to the wash station for cleaning before being put back in service.

3.1B(9) Sterilization Process

Assured Waste Solutions will use a North Carolina approved autoclave for sterilization. This revolutionary technology is the only integrated, automatic, variable operating parameter autoclave in the industry. The vessel is constructed of stainless steel, is 5' in diameter, 11' long and has an operating pressure of 20 psi at a temperature of 260 degrees Fahrenheit. The autoclave holds two(2) carts holding about 300 pounds each of medical waste. Steam for the autoclave is supplied by a 20 hp boiler.

Once the autoclave is loaded, the door is closed and the steam sterilization process in initiated from the control panel. The cycle time of the treatment process is determined by the total weight of the load and the type of material being treated (red bag, sharps or suction containers). The preprogrammed process consists of three (3) phases to assure proper sterilization and allow safe removal of the carts. Phase 1 consists of one or more steam pulses to facilitate steam penetration. Phase 2 includes the residence time required (as per requirements of 15A NCAC) for the waste to reach 250 degrees and obtain a minimum log4 reduction of bacterial spores. Phase 3 is the cool down cycle before the carts can be removed from the vessel. The control cabinet is equipped with a key switch that can change the computer's operating settings to achieve a log12 kill for pandemic or bioterrorist attack conditions. The entire process has no air emissions or offensive odors.

The process parameters are recorded and maintained through the control system. This includes cycle times, weight, temperatures and cycle types. The process data will be retained on tape backup and electronically for three (3) years.

The efficacy of the sterilization process is confirmed using self-contained ampoules of Geobacillus Stearothermophilus biological indicators. After the sterilization cycle is completed, the spores are recovered and analyzed in an incubator to determine kill efficacy. Results of the spore test are recorded in a log and maintained in the office. All time and temperature requirements of North Carolina regulations will be met or exceeded in this process. Frequency of efficacy testing will be once per week, as required in section .1207(2)(d) according to the procedure as described on Exhibit 1 attached.

3.1B(10) Record Keeping

When the door of the autoclave closes and the process cycle started, record keeping automatically begins. The controls electronically records time, temperature and pressure for each cycle. This information/record is maintained on file for three (3) years.

3.1 B(11) Treatment Bin Dumper
The treatment carts are picked up by the forklift and emptied into the hopper of the compactor. After the treatment cart is emptied it is returned to the staging area for reloading of medical waste.

3.1B(12) Emergency Shutdown
An emergency shutdown button is located at the control panel for the autoclave. Also, an emergency shutdown button for the boiler is mounted at the exit door from the plant into the office area.

3.1B(13) Transport to Landfill of Treated Waste
Treated materials are greatly reduced in volume during the vacuum process and inherent melting during the pressure cycles. The treated waste is stored in a roll off container not to exceed seven (7) days until it is transported to a landfill.

3.1B(14) Equipment Operator Training
All employees will receive training and will become knowledgeable of the procedures, equipment and sterilization process. Training programs are oriented towards maintenance and safe operation of the facility.

3.1B(15) Maintenance Equipment
Employees will use maintenance schedule and inspection sheets to monitor and inspect the facility. Visual inspection of all the equipment will be conducted daily to insure that it is in proper working condition. Any equipment in need of repair or maintenance will be removed and replaced, or repaired immediately. A copy of the maintenance, inspection and monitoring plan and its inspection schedule are attached to this Operating Plan.

3.1B(16) Plant Operations Office
The plant will under the supervision of a lead person located in the windowed plant operations office. This office will provide an area to oversee all the plant operations and perform all the required paperwork and record keeping.

3.2 ONSITE TRAFFIC PATTERNS
Vehicles containing untreated waste will enter the facility and approach a designated parking area or dock door determined by the shift operator. Vehicle traffic will pass through a designated gate gaining access to the loading and unloading area. All vehicles carrying untreated waste will enter the facility through the same gate to the property.

3.3 LOADING AND UNLOADING PROCEDURES
Prior to leaving the facility, the driver will check his daily route sheet to assure that all pickups are scheduled and to plan his course of efficient routing. The driver will also obtain all necessary documents (manifests, reports, etc.) to be delivered to customers. While reviewing his daily schedule, the driver makes notes of the supplies that he may need to deliver to the customers.

The driver will perform a vehicle inspection according to OSHA and DOT regulations..

All biomedical wastes picked up by Assured Waste Solutions are pre-packaged by the customer at the customer's facility prior to loading into the truck. A biomedical waste manifest tracking form is completed for each pickup and signed by the customer acknowledging proper segregation and packaging. Assured Waste Solution's sorting, inspecting and recording procedures are described in section 3.4 below.

When all containers are properly marked and coded, the driver will stack the containers across the interior of the vehicle body using care not to damage or tip the containers. Each row of containers are secured using cargo retaining straps to prevent tipping. The driver will lock the vehicle upon completion of loading at each customer location.

Upon arrival at the treatment facility the driver will report to the transportation manager or shift supervisor on duty. The vehicle will be unloaded under the direction of the shift supervisor.

While unloading, the responsible shift supervisor will verify that all containers, boxes, carts, and bins are manifested and accounted for. All required paperwork will be handed over to the shift supervisor or the transportation manager.

During the unloading, containers designated for incineration are set aside and staged into a holding area for transport to an approved incinerator. At the time of the transfer to an incineration facility, a new manifest is prepared for proper receipt of these materials at the incineration facility. This waste will be transferred within thirty (30) days from date of receipt and is stored in an in-plant cooler at 40 degrees until it is picked up by the hauler to transport direct to the incinerator.

After all biomedical waste is unloaded, the driver will complete a visual inspection of the vehicle. All vehicles are cleaned/disinfected when visibly soiled. If a leak is noticed anytime a vehicle contains medical waste, the leaking substance will be collected in a bucket, absorbed in kitty litter and dumped into a bag. The bag will then be treated in the autoclave before being disposed of in the trash container. Any soil contamination will be picked up and disposed of in a similar manner. The leaking container will be located in the vehicle and removed immediately and disposed of according to normal treatment procedures. The vehicle will be cleaned and disinfected before being returned to service.

3.4 SORTING, INSPECTION, AND RECORDING PROCEDURES

When handling containers, all personnel in contact with containers will ensure that the utmost care is taken to prevent damage to containers and that spills are prevented. Employees will wear proper protective equipment (PPE) at all times while handling waste containers.

Prior to moving any containers from the customer's storage area to the vehicle for loading, the driver will inspect each container to verify that it meets the following conditions:

a) Each container will be properly sealed and taped as per requirements of 15A NCAC 13B.1204 before transport to the facility.
b) Each container must not be damaged (crushed, cut, bent, or leaking).
c) Each container must be in an upright position.
d) Any improperly packaged containers will be reported to the customer for repackaging. Assured Waste employees will not assist in the packing procedures.

Once all containers are inspected, the driver will transport them to the vehicle using any method that will not damage or tip the containers.

When loading containers into an Assured Waste vehicle, each container received from a customer will be marked or labeled as follows:

a) Customer account number
b) Customer location information
c) Transporter location information
d) Individual container number

(Assured Waste Solutions barcode label provided to customers contains all the above information).

When all material is properly identified, the driver will load the containers into the truck as described in above section 3.3. The driver will then complete the waste manifest, obtain an authorized customer representative signature and leave a copy with the customer. Prior to departing the customer's premises, the driver will re-inspect the containers to ensure they are properly stacked, not damaged, and show no visible signs of leakage. The driver will then update his route sheet and continue to his next stop or return to the Assured Waste facility.

When unloading containers or boxes at the Assured Waste facility, the plant operators will weigh each container and record its weight with a barcode scan. The transportation personnel will review each manifest for accountability each day of all containers, and note any discrepancies on the manifest or in the computer system to provide notes to customer service.

3.5 HOURS OF OPERATION

The Assured Waste facility can operate 24 hours a day, 7 days a week for treatment processing. Office hours are Monday through Friday from 8:00 AM to 5:00 PM. Independent transporters delivering pre-manifested waste materials will be accepted by prior appointment only.

3.6 ACCESS CONTROL

A lockable and video recorded powered gate will be provided for access into the facility. The gate will be closed at all times with plant access provided only through a keypad or remotely after proper identification. All doors to the facility will be locked prohibiting unauthorized entrance from the outside and secured at all times. The main entrance to the building and office areas will be open during normal business hours only. After hours, all doors to the facility will remain closed and locked prohibiting unauthorized outside entry with the exception of dock

doors being utilized for operations. The entire facility is protected by a security system that will alarm when activated by an unauthorized intruder and notify police and management.

All visitors to the facility are required to sign the visitor's log located in the front lobby. Under no circumstances will Assured Waste allow and unescorted visitor to enter the facilities treatment area.

3.7 TREATMENT/STORAGE AND CAPACITY LIMITS

Assured Waste Solutions is locally permitted to operate the treatment facility at 148 Boxwood Lane, Gastonia, NC. Permitted capacity is based on the maximum waste treatment capacities of the processing equipment, including future additions. Assured Waste will operate the Gastonia, NC facility with the currently permitted two (2) steam sterilization units not to exceed 12,000 pounds per day or 4 million pounds per year each. Based on future expansion capabilities of the facility, the total capacity can be increased to 16 million pounds per year or 1.2 million pounds per month. The actual treatment capacity of each piece of equipment will vary based on the waste type, density, liquid weight, handling procedures, operator interface, and efficiency protocols. Before any future autoclaves are installed, Assured Waste will notify the appropriate state agency for approval to do so and increase its financial assurance package as specified by the state of North Carolina.

All untreated waste is stored in a secure area located inside the facility or in enclosed, locked transport vehicles located within the secure area of the premises to await processing. Storage of untreated and treated waste at the facility will be based in accordance with 15A NCAC 13B Sections .1206 and .1207(1), based on the seven (7) day or refrigerated time status. Treated waste storage is maintained on the premises in a secure area awaiting transport for final disposal.

4.0 WASTE INSPECTION PLAN

Waste containers are packaged and sealed by the generator prior to pick up by Assured Waste drivers. Due to the nature of biomedical waste, health hazards preclude all Assured Waste personnel from opening boxes or cartons of waste prior to dumping into the treatment carts at the facility. Assured Waste enforces the defined protocols on the pre-approval manifests forms certified by the generator that the contents are in accordance with Assured Waste restrictions and regulatory compliance. Assured Waste will not ship or accept for shipment waste that is not packaged in accordance with the requirements of 15A NCAC 13B Section .1204.

5.0 BYPASS AND RESIDUAL PLAN

All processed waste from the facility will be treated in the approved treatment units and disposed in a permitted municipal solid waste landfill. Untreated waste may at times be transferred to a treatment facility other than Assured Waste during equipment maintenance downtime or due to logistics situations. Untreated waste being transferred from the Assured Waste facility will be manifested to track the materials from Assured Waste to a site referred to in the Contingency Plan with prior approval from that facility. Manifest documentation will also indicate the tracking of waste transferred from the generator site or transfer station site directly to a

contingency facility in such event. Requirements of 15A NCVAC 13B, Sections .1206 and .1207(1), will be adhered to at all times when the transfer of waste is required. Storage times will not exceed seven (7) calendar days without required refrigeration.

6.0 MAINTENANCE, INSPECTION AND MONITORING PLAN

6.1 EQUIPMENT MAINTENANCE

6.1A Preventative Maintenance

Preventative maintenance is designed as an aid in setting up a schedule of regular inspections and checks to determine the actual condition if the equipment and to maintain it in proper working order. The systematic use of a preventative maintenance program may be expected to reveal any potential adverse condition in the early stages when the remedy is relatively simple and inexpensive. This operating plan provides an overview of the manufacturers Equipment Operating Manuals.

6.1B Periodic Inspections (Steam Sterilizer and Boiler)

The treatment equipment should be kept clean at all times and special attention should be given to the safety pressure interlock system to guard against sticking of parts.

Check accuracy of instruments, gauges and thermocouples. Also check relief valves to see that they relieve at proper pressure.

Make sure in-line trap drains from steam supply line to vessel are functioning properly.

Frequently inspect flanged joints and other pipe connections.

Test relief valves at least once every year.

6.1C General Inspection and Maintenance

The following procedures should be performed at regular intervals as indicated. This frequency is the minimum and should be increased if usage of the autoclave demands.

Safety Valve: In accordance with the National Board of Inspections Code, periodic checking of the safety valve operation should be performed. Periodic inspection of the equipment by a qualified inspector is advisable. Assured Waste conducts inspections of all pressure vessels and safety valve operation in accordance with the NC Department of Labor, Boiler Safety Bureau.

6.1D Routine Maintenance

Prior to performing maintenance, the control switch must be turned off, facility power to unit disconnected, and accessories must be cooled to room temperature.

Employees shall wear the proper PPE when cleaning or maintaining all equipment.

Daily Maintenance (Start of Shift):

1. Check that supply steam pressure is in range.
2. Check that compressed air pressure is in range.
3. Check that water feed is open.
4. Check door seal for nicks or abrasions, replace if necessary.
5. Check cart rollers that they are free of any debris and smooth rolling.
6. Check that vessel interior is free of any debris and drain is clear.

Weekly Maintenance:

1. Examine vessel and pipe insulation and covers for damage, repair if necessary.
2. Wipe down exterior surfaces and piping.

Quarterly Maintenance:

1. Check, Clean, Adjust the following:
   - Steam pressure regulator
   - Air pressure regulator
   - Vacuum pump seal water flow
   - Cooling water nozzles and flow
   - Main drain trap
   - Vessel interior
   - Control cabinet interior
   - In-line filter screens
   - Cart rollers
   - Door latch operation
   - Calibrations, scale, thermocouple, pressure transducer (full calibration annually)
2. Lubricate cart wheels
3. Lubricate door hinge

6.2 INSPECTION SCHEDULE

6.2A Site Security

1. Outside lighting will be inspected weekly and bulbs replaced as necessary.
2. Security gates and locks will be inspected monthly.
3. Warning signs will be inspected quarterly for proper visibility.

6.2B Safety, Emergency and Personal Protective Equipment (PPE)

The following equipment and PPE will be inspected quarterly for supply, accessibility and condition:

1. Gloves
2. Eyewear
3. Aprons
4. Disposable Coveralls
5. Rubber Boots
6. Face Masks
7. Goggles

8. Duct Tape
9. Hard Hats
10. Respirators
11. First Aid Kit
12. Eyewash Station

Fire Response Equipment

All fire extinguishers inside the facility will be inspected monthly to check for damage, pressure leakage and accessibility. Any damaged extinguishers will be removed from service and repaired immediately.

Spill Cleanup Equipment

All materials and equipment used for spill cleanup both in the plant and carried on all vehicles will be checked quarterly for supply and accessibility. These items include:

1. Absorbent material (kitty litter)
2. Spill Kits
3. Bucket
4. Brooms
5. Shovels
6. Trash Bags

Storage Containers

All storage containers are inspected daily during the normal operation of the plant. These include corrugated boxes and reusable containers coming into the plant for processing.

7.0 WASTE TREATMENT CONTINGENCY PLAN

In the event of equipment failure or plant shutdown, Assured Waste will ship untreated waste to permitted and approved facilities. In such an event, the requirements for storage and transport under 15A NCAC 13B will be maintained.

8.0 EMPLOYEE TRAINING PROGRAM

Assured Waste Solutions, LLC bases its training program on several sources: (1) Job position and company procedures training, (2) Regulatory requirements (EPA, DOT, OSHA). This policy establishes the specific training categories for which each employee must receive instruction and indoctrination. The categories as outlined above are as follows:

A. Job description and company procedures training:

1) Drivers are instructed in the following topics:

a) Company policies
b) Company benefit plans
c) Bloodborne Pathogens
d) Emergency action plan
e) Hazard communication
f) Lockout/Tag out
g) Personal protective equipment
h) Permit confined spaces
i) Accident and injury reporting
j) Fire extinguisher use

k) DOT hours of service
l) DOT hazmat
m) Substance abuse and alcohol misuse
n) Waste acceptance
o) Pre/post trip inspections
p) Accident/warn devices
q) Access to exposure and medical records materials
r) Backing procedures
t) Driver training
s) Proper lifting methods

2) Treatment unit operators are instructed in the following topics:
   a) Company rules
   b) Permit confined spaces
   c) Company benefit plans
   d) Spill cleanup procedures
   e) Equipment operation
   f) DOT hazardous materials
   g) Bloodborne Pathogens
   h) Radiation training
   i) Hazard communication
   j) Accident/injury reporting
   k) Personal protective equipment
   l) Fire extinguisher use
   m) Waste acceptance protocol
   n) Hand/power tools
   o) Container wash training
   p) Emergency eyewash/shower
   q) Emergency action plan
   r) Access to medical records
   s) Proper lifting
   t) Machine guarding
   u) Lockout/tag out
   v) Powered forklift
   w) Slip/trip/ladder safety
   x) NC permit requirements

3) Plant managers/supervisors: In addition to having specific knowledge of driver and treatment unit operations and responsibilities, this category of employee is instructed in the following topics:
   a) Service contracts and documentation
   b) Equipment calibration
   c) Purchasing procedures
   d) Operating records management
   e) First aid and basic company required safety program
   f) Emergency management

4) Bloodborne Pathogens Exposure Training: Specific training will be provided to collection and processing employees concerning hazard recognition and control methods related to infectious medical waste as per 29 CFR 1910.1030. The training outline is as follows:
   a) Purpose of Bloodborne Pathogen training
   b) How infection can occur
   c) Terms
   d) Explanation of Hepatitis B and C
   e) Explanation of Human Immunodeficiency Virus
   f) How HIV and HBV infection can occur
   g) MedWaste Exposure Control Plan
   h) Tasks with occupational exposure to bloodborne pathogens

i) Preventing infection
- Engineering controls
- Work practice controls
- Personal protective equipment

j) Hepatitis B vaccine
k) Exposure incident procedures and follow-up
l) Labeling

Records of training will be recorded and kept on file in the plant office. Contingency training will be conducted in intervals prescribed by regulatory authority and company policy, or as facility management deems it necessary for training update.

9.0 RECORD KEEPING

9.0A Operating and Maintenance Records

Operating and maintenance records will be maintained for all treatment processing operations. The plant manager is responsible for report submission in a timely manner. All waste management records, including any documentation provided by the transporter, are maintained for three years and made available for inspection by all regulatory agencies, along with employee training, transportation, and equipment maintenance records.

a) Reports for treatment equipment operation
- Daily log sheets
- Processing records
- Plant Operations weekly reports
- Monthly production reports
- Monthly statistical report
- Monthly maintenance report
- Disposal logs
- Spill report (if required)
- Accident report (if required)

b) Report for Transportation Operations
- Vehicle condition Reports
- Customer manifest for each medical waste pickup
- Spill report (if required)
- Accident report (if required)

c) Report for Transferred Waste Materials
- Customer list
- Shipping facility waste manifests
- Receiving facility waste manifests

10.0 HOUSEKEEPING

In handling medical waste, good housekeeping practices will be implemented at the facility. The outside property will be maintained in a neat appearance by cutting and trimming the grass areas and spraying for weed control on the property. An extermination contract will be in place to control insects, vermin, etc. inside the building and around the perimeter of the building. The company owned trucks hauling medical waste will have spill kits and PPE on board for cleaning spills and leaks. Transporter's vehicles will be inspected and any noticeable leaks or spills will be cleaned and disinfected before the vehicle is released from the facility. For vehicles parked on the property, any leaks seen emitted from the vehicle will be contained in a bucket, the source located and removed from the vehicle. The spill will be immediately cleaned using the spill kit. Any contamination of the ground underneath the vehicle will be removed, placed in a bag and treated in the autoclave. The secured office area will have no carpeting (tile floors) and no contamination will be brought into the office area. Only authorized employees will be allowed in the office area. The plant area will be properly maintained to be clean, orderly and well lit. Spill cleaning materials, hospital grade disinfectants and PPE will be stored in the plant for employees to properly cleanup any spills using the required dwell times. The plant concrete floor will be washed at least weekly, or as required for spill cleaning, into the floor drains and discharged into the sanitary sewer. Management is trained and certified in biohazard cleaning. The autoclave has a cleaning cycle to maintain the inside of the autoclave chamber and the treatment carts. If any additional cleaning is required, the carts will be taken to the wash station where they will be pressure washed using hot water and disinfected before being returned to service.

11.0 COMMUNICATION

Should the treatment facility close for any reason other than normal business hours, the Company will inform the Division of Waste Management, Solid Waste Section, upon the closing, reason for closing and re-opening date.

12.0 EMERGENCY CONTACTS

In case of emergency, contact Plant Management at phone numbers listed in the plant.

For police, fire or medical emergency, call 911 and communicate needs.

State DENR emergency contacts are as follows:

1. Bill Wagner, Environmental Senior Specialist: 828-296-4705
2. Jason Watkins, District Supervisor: 336-771-5092
3. Larry Frost, Environmental Engineer: 828-296-4704
4. Environmental Emergencies: 800-858-0368

Exhibit 1

Periodic Spore Test Procedure

Care and caution is required when performing this procedure. Appropriate Personal Protective Equipment (PPE) must be worn in accordance with facility protocol. This includes safety glasses, impervious gloves and rubber apron when working around Regulated Medical Waste (RMW).

The VariClave has been designed with a comprehensive parametric monitoring, recording, alarm and notification system. This system combined with the extensive testing performed to establish cycle protocols ensures effective treatment of the RMW.

Material required for testing:

1. Raven ProSpore ampoule PS1-4 (Geobacillus Stearothermophilus, approximately 2.4 x 10^4 CFUs)
2. Dry Bath Incubator for ProSpore ampoules, set to 55 degrees C
3. Test Carrier provided by OnSite Sterilization

Procedure:

1. Place two (2), PS1-4 ampoules inside the Test Carrier
2. Set one additional ampoule aside as an un-processed control
3. Carefully place the Test Carrier in the center of the RMW load in the bin.
4. Load the bin into the VariClave following the loading instructions.
5. Initiate the VariClave process cycle.
6. Print a second copy of the cycle report to file with the test log.
7. Note the date, time, cycle number cycle type and weight in the test log.
8. Carefully retrieve the Test Carrier from the bin.
9. Remove the ampoules, place in the incubator along with the control ampoule, and incubate for 48 hours.
10. Inspect the ampoules for color change after 24 and 48 hours of incubation.
11. A color change to bright yellow indicates “Growth” and a failed test. Any other result indicates “No Growth” and a passed test.
12. Note the result on the Test Log and initial.
13. In the event of a failed test result, the protocol for a failed test is as follows:
    a. Check process alarm status and take corrective action if applicable
    b. Reprocess load and retest
    c. If second failure occurs, contact manufacturer to identify potential problem and take corrective action
    d. Reprocess load and retest
    e. Document events

Exhibit 2

Assured Pharmaceuticals

Division of Assured Waste Solutions, LLC, Gastonia, NC

OPERATION PLAN

Date: September 27, 2012

1.0 Building Security

Only authorized personnel will be allowed access to the plant property. Anyone else must be accompanied by a member of management (Security Level One or Two). All employees will adhere to completing the designated entry/exit log assigned to the secure locations of Assured Waste Solutions (DEA cage, pharmaceutical processing room and the vault). All visitors to the plant will complete the designated entry/exit logs located in the front lobby and at the receiving dock before entering the plant. Any secure location entered by a visitor will be accompanied by an authorized employee (Security Level One or Two) and the designated enter/exit log will be completed.

2.0 Employees

Due to the sensitivity of the products handled in the facility, all newly hired employees will be screened by the following methods:

a. Drug screen (5-panel)
b. Criminal background check
c. References provided

All employees will be assigned to one of three security ratings with all having secured access to the facility entrances and limited access to areas within the facility. The three security levels are described below.

a. Security Level One - these employees are registered with the DEA and properly permitted to handle scheduled pharmaceuticals. They have 24 hour card access to the entire building, processing room and vault.
b. Security Level Two – these employees are not registered with the DEA and have limited card access to the entire building and processing room.
c. Security Level Three – these employees are not registered with the DEA and have limited card access to the building and office area but no access to the processing room and vault.

All employees will be personally responsible for understanding and abiding by all the rules and regulations for their assigned duties. This includes reporting for duty at their scheduled time, remaining physically and mentally alert at all times, and dressed in appropriate attire. Any equipment issued to an employee will remain the property of Assured Waste Solutions. If any equipment is lost or stolen, it will be immediately reported to management. All equipment will be returned to Assured Waste Solutions at any time an employee's working status ends.

No illegal drugs or alcohol are allowed on the job or while in company vehicles. Anyone working under the influence of drugs or alcohol will be reprimanded up to and including termination. The use of prescription drugs or over the counter drugs on the job should be considered for side effects and how it could affect the safety of the job. Management can prohibit and employee from working if his performance is impaired. Random drugs testing will be performed on all employees.

Employees with company computers (desk or laptop) will not be allowed to access any social networks when working on the computers. Nor will any personal information be stored on company computers. All company information is confidential and will not be copied and/or removed from the facility unless needed for company business and then only upon approval from management. All company passwords and e-mails will not be altered by employees unless authorized to do so.

It is the responsibility of employees to notify management if they are criminally charged with any crime. Failure to do so will result in corrective action up to and including termination.

3.0 Receiving Responsibilities

All product will enter the plant through the dock receiving area. This means the dock will be secured at all times when product is being processed. All personal bags or packages should be secured either in the employee's vehicle or in a provided locker. There will no bags, packages or containers allowed on the dock area except for those approved for receiving and storing product.

While receiving product into the plant the dock will not be left unattended. When not working on the dock area all doors will remain closed and locked at all times. All pharmaceutical shipments will be immediately received, documented and placed in the appropriate storage area or transport cart.

Proper protocol will be followed when receiving pharmaceuticals. This includes cross referencing each shipment with pre-shipment documents. Containers will not be altered in any fashion upon receipt. If any discrepancies in the paperwork or any appearance of any container being altered or damaged is observed, a Level One manager must be notified immediately and any further handling of product will cease until an investigation is completed.

4.0 Driver Responsibilities

Every driver is responsible daily for making sure that his vehicle is prepared for handling pharmaceuticals. This includes the following checks before leaving the facility:

a. The vehicle is in good operating condition with no body damage
b. There are no containers or packages in the vehicle that are not accounted for
c. The gas tank is over half full (if not, top off the tank before making the first stop)
d. The door locks are functioning properly
e. The alarm is working properly
f. The GPS is installed and functioning

When on the road, the driver must document his start time, arrival time at each customer stop, departure time from each customer stop and return time to the facility.

Any detours from an assigned route or any breakdown must be reported immediately to the dispatcher or management.

When a driver is in possession of pharmaceuticals in his vehicle, he must minimize the time away from the vehicle and, if possible, keep the vehicle in sight when away. The vehicle must always be locked when away from or driving the vehicle.

5.0 Product Pick-up

As a service to our customers, the company will provide inventorying and packaging of pharmaceuticals for shipment to the facility. The procedure to prepare products for shipment is detailed below.

a. Obtain a secure area to work in
b. Scan the products for proper identification
c. Identify any special shipping needs and/or hazardous products
d. Separate products by schedules
e. List products in each shipping box on Form 222, putting a copy in each box
f. Secure the box to avoid tampering by inserting the tag tie through the hole in the rim of the container
g. Document the name of the person packing each box
h. Affix a copy of the shipping label on the outside of the box, listing any special shipping needs and assuring that there are no drug identifications visible
i. Affix the proper schedule identifier (colored round stickers)

When the boxes are ready for shipment, each shipment will be verified through a manifest. The driver will then verify the number of boxes, the boxes are properly sealed with security tape and the boxes are not compromised. Any discrepancy must be immediately reported to management.

A chain of custody will be documented by the following:

a. Driver will verity that the shipment matched the manifest
b. A signature will be obtained from the customer sending the product
c. The driver will then verify and sign that he has accepted possession of the shipment
d. The driver will immediately deliver the shipment to the Assured Waste facility and obtain the receiving person’s signature who then takes possession of the shipment

6.0 Transportation Security

Any vehicle transporting pharmaceuticals will abide by stringent security protocol including the following:

a. Alternate travel routes that will be designated prior to pick up
b. Designated pick up schedules
c. Unique codes printed in each vehicle that are easily viewed by the driver. If there is a security breach, the driver can radio this code to the dispatcher and emergency assistance will be summoned

7.0 In-Plant Handling of Product

When product is delivered to the facility it must be scanned in and signed for by a Security Level One member. The product will then be put into a locked transfer cart and taken to the DEA cage in the warehouse or directly to the vault if a Schedule 1 or 2 drug. When stored in the cage or vault the product must be signed for again by a Security One member. Any non-hazardous product can be stored in the locked room in the plant and does not have to be signed for upon delivery.

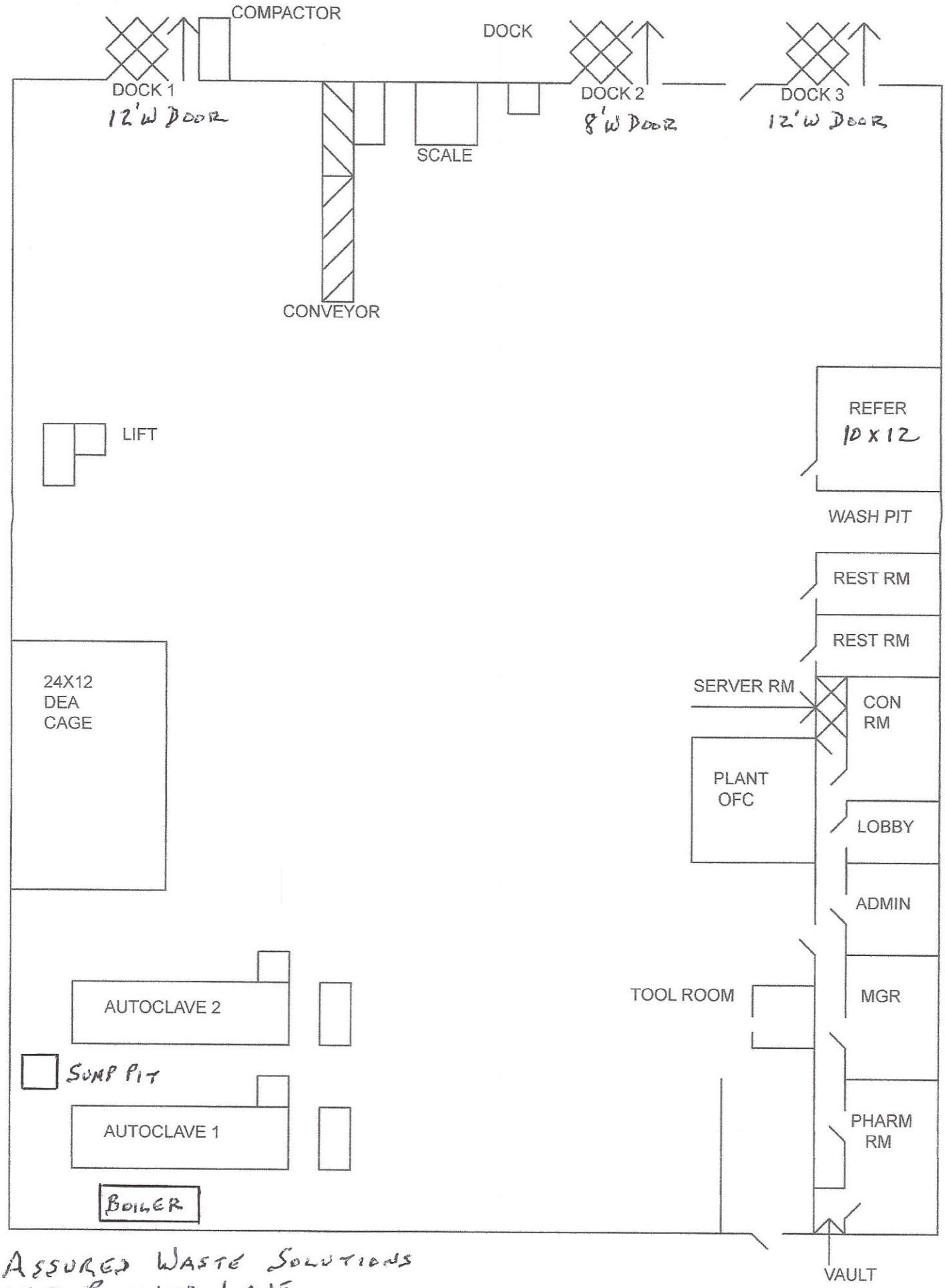
8.0 Processing Room

There will be no personal bags or packages allowed in the pharmaceutical processing room. All personal items must be stored either in the employee's vehicle or in a provided locker. The processing room will be kept clean at all times with no drinks or food allowed in the room.

The door to the processing room will be closed and locked at all times. Access to the room will be only by authorized Security Level One or Two personnel and those people must have the issued access cards and the code to open the door.

When processing drugs in the room, only those drugs being handled will be out of the secured draws or the vault. At no time should pharmaceutical products be left out in the open when the room is left unattended for extended periods of times.

Any lost or stolen access cards will be immediately reported to management and the Director of Security.



ASSURED WASTE SOLUTIONS
148 BOXWOOD LANE
GASTONIA, NC 28054

BB&T

Branch Banking and Trust Company

Business Services

Mailcode: 503-01-02-00
PO Box 1776
265 W Franklin Blvd (28052)
Gastonia, NC 28053
Office (704) 852-5969
Fax (704) 852-5531

October 23, 2012

NC Department of Environment, Health and Natural Resources
Solid Waste Management Div/Solid Waste Section
PO Box 27687
Raleigh, NC 27611-7687

RE: Medwaste Solutions LLC – Name Change

To Whom It May Concern:

We are aware that Medwaste Solutions LLC has legally changed their name to Assured Waste Solutions LLC. We are also informing you that the Letter of Credit dated 11/22/2011 is still in place and valid.

Thank you and please contact me should you have any questions or you may call Lisa Lane, Business Services Officer, at 704-852-5753.

Sincerely,

JoAnn Hunter
Business Services Assistant
704-852-5548

Cc: Lisa Lane