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Plant: 3250 Campus Ridge Road, Matthews, NC 28105 (704) 821-4766
Corporate Office: 6165 Northway Drive, Morrison, CO 80465 (303) 526-9778
e-mail <djschoonmaker@att.net>

BMWNC, Inc.

RECEIVED
JAN 23 2007
SUPERFUND SECTION

January 19, 2007

Permit No.	Date	Document ID No.
36-11	**February 2, 2010**	**9522 was 985**

Mr. Edward Mussler III, PE,
Permitting Branch Supervisor
Solid Waste Section, Division of Solid Waste
NC Department of Environment and Natural Resources
401 Oberlin Road, Suite 150
Raleigh, NC 27699-1646

APPROVED DOCUMENT
Division of Waste Management
Solid Waste Section
Date **April 1, 2010** By **LY Frost**

Dear Mr. Mussler:

This letter and the Operating Plan attached serve as our application for a Solid Waste Permit for BMWNC, Inc. to operate a Medical Waste Treatment facility at 148 Boxwood Lane, Gastonia, NC in accordance with Article 9, Chapter 130A of the General Statutes of North Carolina and subject to the rules promulgated there under.

As you suggested, we have attached a zoning letter showing compliance of this treatment, transfer and reusable sharps container recycling program under their zoning ordinances.

I have written the Operating Plan to include two technologies. One is steam sterilization by autoclave, which is approved in NC for this purpose, and the second is for a chemical treatment technology developed by Oncore out of Texas. We will make the decision as to technology based on delivery times and proven performance.

Why two technologies? I review technologies regularly and track some 90 variations for the treatment of medical waste. Most are questionable, but autoclaving is an industry standard. Our supplier, International Marketing, Salisbury, NC, has supplied units now used by Stericycle for the same purpose. Chemical treatment has also proven to be effective, but is usually not "generically approved", as is the case with autoclave sterilizers. The principals of Oncore, the manufacturer of the chemical treatment system we are considering, will be in touch with Bill Patrakis to go over their ten years of testing of their system and technology and to gain NC approval of their equipment. If they are approved in a timely manner, we will consider this technology and equipment which has some very real benefits to the environment. Whichever way we go, we will advise you in advance of placing any equipment orders.

Received
Solid Waste Section

We would appreciate your expedited handling of this permit request. As I pointed out to you, BMWNC, Inc. plans to do routine, but substantial, maintenance in May at our incinerator at Matthews, NC, and are striving to have the treatment plant in Gastonia permitted and build before that scheduled shut down in order to handle part of the medical waste we collect and treat at the Matthews facility.

Sincerely,

David J. Schoonmaker
President

Attached:
1. Operations Plan
2. Zoning Letter from Gastonia
3. Layout of the proposed facility
4. Rationale for time and temperature in Autoclave Sterilizer

CC: Joe Mayernik, CEO, Healthcare Waste Solutions
Rich Geisser, Director of Operations East
Norman Martin – Facility Manager, BMWNC

BMWNC, Inc.
Steam Sterilization Facility
Gastonia, North Carolina

OPERATIONS PLAN

Date: January 18, 2006

1.0 **INTRODUCTION** BMWNC, Inc., (a wholly owned subsidiary of Healthcare Waste Solutions, Inc. which owns and operates five autoclave facilities, one incinerator, and five transfer stations for medical waste), plans to build and operate an autoclave plant at 148 Boxwood Lane, Gastonia, NC. The site, consisting of a 10,640 square foot warehouse on approximately two acres is properly zoned (zoning letter attached) and suited for medical waste treatment, transfer of medical waste for appropriate treatment off site, for handling reusable sharps containers, transportation of untreated and treated medical waste. The facility can house either two (2) steam sterilization units (autoclave) or two (2) chemical treatment units. Treated waste will be compacted into roll offs prior to being transported to a permitted Sub-Title D Landfill, municipal or waste to energy incinerator, to other properly permitted medical waste treatment facilities. The operating parameters for waste treatment are detailed in this Operating Plan, with applicable requirements set forth in the NC GS 130A-294 solid waste management program and including 15A NCAC 13B, (.1200, .1201(e), .1201(4) .1202, .1203,.1205, 1206, 1207(1), (2) and (4), and .1207(1))

2.0 **Facility Identification** BMWNC, Inc., 148 Boxwood Lane, Gastonia, NC, Federal ID# 56-1934817 , Mailing Address: 3212 Campus Ridge Rd., Mathews, NC 28105, Attn: Norman Martin, Plant Manager.

3.0 **Operations:** The facility is operated in accordance with rules and regulations set forth by the division of Waste Management, North Carolina and the City of Gastonia, NC. The manufacture's Operating Manuals are kept on file at the Plant Manager's office. All employees, based on job description, shall receive training as to the contents of the manual, safety procedures and practices, operation, maintenance, OSHA rules, including lock out, tag out and Bloodbourne Pathogens, servicing and maintenance of the equipment and safety practices. BMWNC, Inc. accepts prepackaged boxes, reusable and disposable containers of various sizes containing medical waste, sharps in containers or reusable containers, pharmaceutical waste from generators, BMWNC owned and operated transportation equipment, and roll offs and vans from third party licensed haulers and transporters. Wastes requiring incineration will be transferred to BMWNC's incinerator at Matthews, NC or other properly permitted incinerators capable of treating by pass waste. The accepted waste is treated by steam sterilization units, (autoclave) or by chemical treatment. Treated waste would then be disposed of at a Sub-Title D landfill or, if available, at a municipal or waste to energy incinerator.

3.1 **General Operations:** Waste is transported to the treatment plant from generators by way of BMWNC drivers or licensed Transporters with whom BMWNC contracts treatment services. It is received in DOT approved corrugated boxes, reusable and other disposable containers, roll off containers and sharps transporters. The containers are offloaded at the truck docks or the bay door. All waste received shall be manifested and the customer and generator recorded as required by NC regulations. Upon receipt, containers are recorded as to weight, type of container and number of containers. Any waste requiring incineration or transfer is trans-loaded into a trailer or truck and sent to BMWNC's Matthews, NC or other properly licensed and permitted incinerator or treatment facility. Personnel will use hand trucks, forklifts or conveyors to unload or transfer medical waste. Once accepted, the waste is loaded into treatment bins and treated in one of the sterilizers or chemical units. After treatment the waste is compacted into a roll off container for shipment to a permitted disposal facility.

3.2 **Detailed Operations**

3.2.1 The sterilization or chemical treatment units are PLC controlled and utilize paper recorders that record cycle times, temperature, pressure, or chemical additions, pH and other parameters to demonstrate treatment efficacy.

3.2.2 BMWNC, Inc. provides collection and/or treatment services to the health care industry in the states of VA, WV, TN, GA, NC, SC, DC, MD, FL and KY. The service, if done directly with the generator, includes supplies, boxes or containers, reusable sharps containers, and the like, with labels, manifests, barcodes and eventually radio chips for tracking, customer identification, and other DOT requirements. For other collection companies, the facility would receive, log, treat or reship, wash containers, and provide other services needed to meet the healthcare needs in the region and/or the licensed transporter.

3.2.3 Medical waste will be transported in trucks and/or trailers by employees of BMWNC, or by licensed Transporters. Medical waste is shipped to the facility in approved corrugated boxes, reusable containers, roll offs, disposable containers and in sharps transporters that meet DOT requirements. BMWNC does not transport, accept, treat or transfer medical wastes that are not properly packaged or classified in accordance with 15A NCAC 13B, section .1204.

3.2.4 BMWNC shall also maintain compliance with the requirements of section 15A NCAC 13B.1205, which includes:

3.2.4.1 Rejection of waste that is improperly packaged

3.2.4.2 Medical waste shall be transported in a manner that prevents leakage of contents of the package

3.2.4.3 The integrity of the package shall be maintained at all times

3.2.4.4 The labeling and marking of the package shall be maintained at all times.

3.2.4.5 All loads containing medical waste shall be covered during transportation

3.2.4.6 The universal biohazard symbol shall be displayed on all transportation vehicles, in accordance with the US DOT standards and 49CFR 172 Subpart F.

3.2.4.7 Medical waste, both that is treated on site, or that transferred, shall be treated or delivered to a permitted storage or treatment facility within seven calendar days of the date of receipt from the generator.

3.2.4.8 If longer storage than seven (7) days is ever required, it shall be refrigerated at temperatures between 35 and 45 degrees Fahrenheit and shall be maintained at these temperatures until treated or transferred.

3.2.4.9 A contingency plan shall be prepared and maintained in each vehicle, as well as a emergency response kit, used to transport medical waste. The operator of each vehicle shall be knowledgeable of the plan and use of the kit.

3.2.4.10 Vehicles used for the transportation of 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.

3.2.4.11 While transporting medical waste, vehicles are prohibited from transporting any material other than solid waste and supplies related to the handling of medical waste.

3.2.5 The medical waste containers are offloaded at the dock by hand truck, forklift or conveyors, or by rolling them off if the container has wheels, (such as sharps transporters, larger reusable plastic containers) by employees. Thus, containers shall remain intact from the generator's site during treatment and up to and until transfer or treatment. Containers shall not be compacted before transfer or treatment. All reusable containers shall be constructed or smooth and easily cleanable materials.

3.2.6 Properly classified medical waste that cannot be treated by a sterilizer or chemical treatment process are segregated and staged for further transport to a licensed and appropriate treatment facility, most often to BMWNC's incinerator in Matthews. Shipping documents are utilized to track this material to the proper treatment and disposal facility. No waste shall be accepted that does not meet the packaging requirements of 15A NCAC 13B .1204.

3.2.7 All containers that have been scanned, recorded, and weighed are conveyed to a dumping platform or hydraulic tipper/dumper. Disposable and/or the contents of the reusable containers are then dumped into the treatment bins, or in the case of a chemical

treatment unit, into the treatment chamber itself. After dumping, the reusable containers are conveyed to a container washer where they are cleaned with hot water and a disinfectant. The dumping process is repeated until the treatment bins or chamber are full or until they have the proper weight in them for loading into either the sterilizer(s) or chemical treatment units (2) for treatment.

3.2.8 In the case of a sterilizer, once the treatment bins are filled with untreated medical waste, the bins are conveyed via forklift to a staging position. Treatment bins are then loaded into the autoclave by placing them on a scissor lift that had rollers or chains to load them into the autoclave. Unloading of treated waste in treatment bins is done the same way, after which they are staged to be dumped into a compactor that feeds directly into a compactor vessel for shipment to an approved landfill or, if available, to a waste to energy incinerator. Once emptied, the bins are available again for refill with untreated medical waste.

3.2.9 In the case of reusable sharps, the sharps containers are unloaded from a transporter, are then loaded on a automated sharps washer, which opens the container, empties the contents into a treatment bin or reusable tub, and then washes the container, after which they are detailed and loaded back into transporter carts. Once the bin or container used to receive contents if full, they are moved to the sterilizer or chemical treatment unit, and the contents are treated the same as other medical waste.

3.2.10 In the case of a chemical treatment unit, the waste is loaded into the unit, the automatic cycle is run, and after treatment is loaded into a treatment bin and staged for compaction and loading into a compactor vessel for transport to an approved landfill or alternate waste to energy incinerator.

3.2.11 BMWNC will either use up to two (2) National Board and NC Department of Labor approved pressure vessels or approved chemical treatment units. (The choice of technologies will be confirmed with the appropriate NC agencies once a decision is made on the choice of these two approved technologies.) In the case of an autoclave, the vessel will be constructed of carbon and stainless steel, are 8' in diameter, and 32 feet long, each holding up to six coated bins for easy handling, dumping and reuse. The autoclave is fed steam provided by a 250 hp fire tube boiler that is National Board and NC Department of Labor approved.

3.2.12 Once either the autoclave or chemical treatment unit is loaded, the door is closed, the process is controlled by a PLC unit. Autoclave units will go through three cycles, first a pre vacuum stage to evacuate ambient air, then steam injection of steam to reach and maintain a temperature of 275 degrees or higher at up to 80 PSI. The equipment shall have a gauge to measure pressure on each cycle. When the temperature in the autoclave is reached, the waste

is treated for 30 minutes at 275 degrees or higher, to achieve efficient pathogen kill at the core of the load. When complete, the steam pressure is released through a condenser that reduces steam release to the atmosphere, and then a second vacuum is applied, which reduces steam condensate and odor in the building. Once done, an alarm alerts employees to unload the autoclave. For a chemical treatment unit, the cycle time is 15 minutes, which has proven efficacy data, and again the unit is unloaded into treatment bins for dumping at the compactor.

3.2.13 Efficacy of both the sterilization process and the chemical treatment is confirmed at least once per week (as per section .1207(2)(d)) using a dual species (Bacillus Atrophaeus and Geobacillus Stearothermophilus) biological indicator. Also used in the sterilization cycle only is a heat sensitive indicator strip to determine kill efficiency.

3.2.14 Both systems log each cycle on a continuous chart recording system, showing time, temperature, and pressure for the sterilizer, and time, chemical addition, pH and temperature for the chemical system. Data will be retained on file for three (3) years.

3.2.15 The bins are picked up by forklift and emptied into a hopper on the compactor. When emptied, they are staged for reloading of medical waste.

3.2.16 Emergency shutdown buttons on located on each piece of treatment equipment, both types on the control panel.

3.2.17 Treated materials are then transported, based on the requirements of the permitted landfill or waste to energy incinerator. BMWNC anticipates using 20 to 25 foot compactor vessels for transport on a roll off truck, both supplied by the landfill or incinerator. The units will have load cells to prevent overloading.

3.2.18 Operator training shall comply with DOT, OSHA and NC Department of Labor and Solid Waste regulations. This includes training on the equipment, process, lock out/tag out, regulations that apply to the permit and process, and safety. Frequency includes training upon being hired, and then periodic refresher courses as required in the applicable regulations and by company policy.

3.2.19 Maintenance of equipment will use the maintenance inspection frequency, service, replacement of parts, and other requirements recommended by the manufacturer of the key equipment and verified using inspection sheets. Inspections will be on a daily, weekly, monthly or other schedule as recommended. Visual inspection of all equipment will be done daily to insure proper working conditions. Any equipment in need of repair or maintenance will be done when inspected or on a schedule, and non repairable equipment replaced. A schedule of maintenance

required will be posted at the plant and the tasks will be part of the training of employees.

3.2.20 On site traffic patterns include receipt of trucks or trailers, moving these to the loading dock when scheduled for processing or transfer, loading and then dispatch. All trailers or trucks with medical waste on board will be kept locked on the yard. Storage logs will be kept to insure that waste is treated within seven (7) days or, if refrigerated as noted above, for no longer than the requisite number of days.

3.2.21 Loading and unloading will be scheduled by the dispatcher. Upon arrival at the facility, the manifests that accompany each load, (the number of manifests vary by the number of generators' containers in the truck/trailer) and other paperwork is delivered by the driver to the dispatcher or plant supervisor. The load is logged in with time and date. If available, the load is placed at the dock for treatment of the medical waste, or assigned a parking space for later unloading and treatment. Medical waste requiring incineration or other off site treatment will be staged and loaded into a trailer for transport. The maximum time that this transfer trailer can be stored on the yard is from the time the first container is staged until the load is shipped, that being is seven (7) days. The transfer truck will be cleaned/disinfected when visibly soiled or otherwise immediately in response to a spill or leakage using the onboard spill kit and disinfectant.

3.2.22 When BMWNC collects medical waste, all personnel in contact with containers will ensure that 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. Inspection of containers offered for shipment will verify:

3.2.22.1 Each container is properly sealed and taped (boxes) as per requirements of 15A NCAC 13B.1204 before transport,

3.2.22.2 Each container must not be damaged (crushed, cut, bent or leaking),

3.2.22.3 Each container must be in an upright position

3.2.22.4 Any improperly packaged containers will be reported to the customer for repackaging. BMWNC employees will not assist in the packing procedures.

3.2.22.5 Once inspected and loaded, the driver will transport them to the vehicle in a manner that will not damage or tip the container and shall deliver them within seven (7) days of the shipment from the generator.

3.2.22.6 The container is marked or labeled so that the generator's name, address and telephone number, transporter's name, address and telephone number,

treatment facility's name, address and telephone number, date of shipment and "INFECTIOUS WASTE" OR "MEDICAL WASTE" and the BioHazard symbol, (in accordance with the DOT standards and 49 CFR172 Subpart F), is visible on the outer surface of the container. The bar code can contain this information or the boxes must be so labeled.

3.2.22.7 The manifest shall include the amount of waste by number of packages, date shipped off site, name of the transporter and the name of the treatment facility. This shall become part of the record and be kept on file at the treatment plant for three (3) years.

3.2.22.8 A copy of this plan shall be kept at the treatment facility and maintained, including any amendments or modifications made here after.

3.2.23 Upon loading, the driver will complete the waste manifest, obtain an authorized customer representative signature and leave a copy with the customer.

3.2.24 Upon receipt and unloading, the operator will weigh each container and record its weight, if applicable using the bar code system, and note any discrepancies on the manifest or in the computer system to provide notes to customer service.

3.2.25 Any waste picked up for shipment, transferred or staged for transfer shall be stored in a manner that maintains the integrity of the packaging at all times and maintains the labeling and markings.

3.2.26 BMWNC processing facility can operate 24 hours a day, 7 days a week for treatment. Office hours will be Monday through Friday from 8:00 AM to 4:00 PM or extended hours as needed.

3.2.27 Access controls when the office or plant is not in operation will be accomplished through locked doors, alarms and the like, and the trucks in the yard will remain locked when parked for temporary storage. Only authorized personnel shall have access to areas of the facility where regulated medical waste is stored.

3.2.28 All areas used to store regulated medical waste shall be kept clean and no storage shall be permitted in areas where there is carpeting or floor coverings with seams. Vermin and insects shall be controlled.

3.2.29 All floor drains shall discharge directly to an approved sanitary sewage system. Ventillation shall be provided and shall discharge so as not to create nuisance odors.

3.2.30 This Operating plan shall serve as guidelines to ensure continued proper management of regulated medical waste.

3.2.31 Treatment volume limits are set based on the capacity of the autoclaves or chemical treatment equipment. The autoclaves can treat 3,500 lbs. per hour each, or 7,000 lbs. per hour and the chemical treatment equipment can treat 2,500 lbs. per hour each, or

5,000 lbs. per hour. The plant shall be limited to process no more than 96 tons per day and transfer up to 96 tons per day.

3.2.32 Records of regulated medical waste shall be kept at the facility by maintaining the manifest, but in addition, the facility shall record the weights received, number of packages on each manifest, date treated and the name and address of the ultimate disposal facility.

3.2.33 Storage of untreated waste shall be in a secure place, either within the locked building or in locked transport equipment. Storage of untreated and treated waste at the facility will be based in accordance with 15A NCAC 13B Sections .1206 and .1207(1). Treated waste is maintained either in bins or in the compactor vessel awaiting transport for final disposal. No more than 30 tons will be stored on the property at any one time.

3.2.34 Processed waste from the facility will be treated in the approved landfill or at a waste to energy incinerator. Untreated waste being transferred from the facility will be manifested to track the materials from the BMWNC treatment facility to an approved treatment facility, usually the BMWNC incinerator at Matthews, NC. Requirements of 15A NCAC 13B Sections .1206 (1) through (8) will be adhered to at all times when transfer of waste is required. Storage times will not exceed seven (7) days without refrigeration.

3.2.35 In case of equipment failure or shut down, BMWNC will ship untreated waste to a permitted and approved facility, with a primary destination being the BMWNC incinerator at Matthews, NC. In such event, the requirements for storage and transport under 15A NCAC 13B will be maintained.

3.2.36 Employee Training is based on job description, responsibilities, and regulatory requirements under the NC Division of Solid Waste, NC Department of Labor, the EPA, DOT, and OSHA

3.2.36.1 Training will include, as applicable, company policies, Bloodborne Pathogens, Safety, Lock out/Tag out, Hazard Communication, DOT hours of service, OSHA and EPA regulation training, Personal Protective Equipment, accident and injury reporting, Access to Exposure and Medial Records Materials, substance abuse and alcohol misuse, proper lifting methods, entry into confined spaces, DOT Hazmat, and driver training.

3.2.36.2 Specific training will apply to operators of the autoclave sterilizer or chemical treatment equipment, the reusable sharps washing system and containers, the tub washing station, and other equipment as required by the manufacturer and NC Permit requirements.

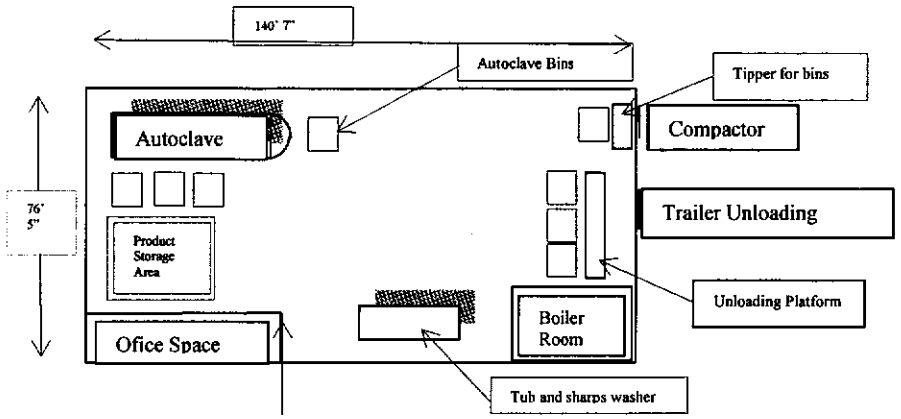
3.2.37 Record keeping shall include daily logs and time and temperature charts, plant operations weekly reports and production summaries, statistical reports, monthly maintenance report, volumes received

by country and state, logs of transferred materials and sites where transferred, log of disposal of treated waste, spill reports and accident reports.

3.2.38 Volume reports to NC – on or before August 1st of each year, BMWNC shall report the amount of waste received (in tons), amounts transferred, amounts treated to the NC Solid Waste Section on forms prescribed by the Section. It shall include wastes handled from July 1 to June 30th of the previous 12 months, the amounts received, treated or transferred in tons on a monthly basis and a copy of the report sent to the County Manager from which waste was received.

3.2.39 Steam sterilization shall not be employed for pathological waste and for chemical treatment conducted at BMWNC, (unless specific approval is granted based on the chemical treatment equipment and testing data submitted at a later date).

140' 7"
140' 7"


140' 7"
Autoclave Bins
Tipper for bins
Autoclave
Compactor
76' 5"
Trailer Unloading
Product Storage Area
Unloading Platform
Boiler Room
Ofice Space
Tub and sharps washer

City of Gastonia
Zoning Office
PO Box 1748
Gastonia, NC 28053

January 17, 2007

David J. Schoonmaker
6165 Northway Drive
Morrison, CO 80401

Re: Zoning Verification
148 Boxwood Lane
City of Gastonia, Gaston County, North Carolina

To Whom It May Concern:

The City of Gastonia's Zoning Office has reviewed the property referenced above and hereby certifies the following:

1) The subject property is located within the City of Gastonia's Planning Jurisdiction.
2) The City of Gastonia does have a zoning ordinance, which regulates the use of the subject properties.
3) The subject property is located within the I-G, Industrial General zoning district.
4) The proposed use of the property for the operation of a warehouse/manufactured goods class I, as related to medical waste, would be a permitted use within the I-G zoning district, which includes the receipt of medical wastes, the processing of and/or treatment of the medical wastes and the shipment of the processed wastes to approved disposal facilities.
5) All processing and/or treatment of the medical wastes should be conducted within the building.
6) A check of the records within the Inspection Division Office did not show any violations relating to the zoning ordinance or building codes.

Please feel free to contact me at 7040 866-6746 with any questions you may have.

Sincerely,

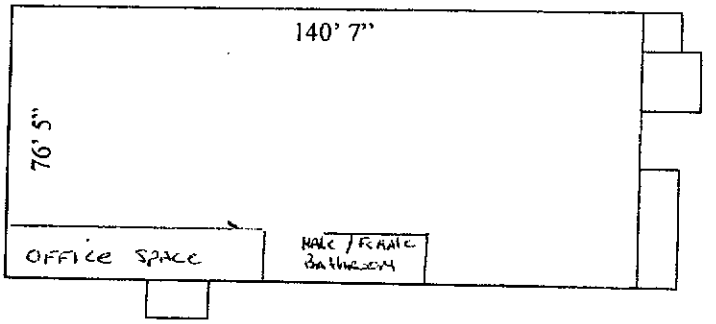
Drew T Pearson, CZO, CFM
Zoning Administrator

The James B. Garland Business Center
150 S York Street
phone 704-866-6746 - fax 704-836-0044
drewp@cityofgastonia.com

EXHIBIT "A" - Continued

Barkley Facility
Gastonia, North Carolina

One Story Brick Building



Not to Scale

Sewer Pipe as 8" Main and the Gas as a 4" Main and the Electric as 400 amps, 3 phase, 240/400 volts.

Barkley Facility
Gastonia, North Carolina

BUILDING DESCRIPTION

Location:	148 Boxwood Lane Gastonia, North Carolina
Size and Configuration	
Total:	10,640
Dimensions:	
Manufacturing:	8,640
Office:	2,000
Site Acreage	2 acres
Zoning	
Number of Floors	One
Construction	
Date of Construction:	1968
Floors:	6" reinforced Concrete
Walls:	Brick on Block
Roof:	Built up tar & gravel
Ceiling Heights:	14'
Column Type:	25' X 50'
Column Spacing:	Circular Steel
Lighting:	Fluorescent
Restrooms:	Plant: 2 Male, 2 Female Office:
Utilities	
Water:	8" main, supplied by City of Gastonia
Sewer:	8" main, supplied by City of Gastonia
Gas:	4" main supplied by City of Gastonia
Power:	400 amps, 3 phase, 240/400 volts, supplied by Scana

Plant: 3250 Campus Ridge Road, Matthews, NC 28105 (704) 821-4766
148 Boxwood Lane, Gastonia, NC
Corporate Office: 6165 Northway Drive, Morrison, CO 80465 (303) 526-9778
e-mail <djschoonmaker@att.net>

36-11 TP

BMWNC, Inc.

March 21, 2007

Ms Sherri Stanley,
Solid Waste Section, Division of Solid Waste
NC Department of Environment and Natural Resources
1646 Mail Service Center
Raleigh, NC 27699-1646

RE: Application for Permit to Construct
Proposed BMWNC Medical Waste Treatment Facility
Gaston County, NC

Dear Ms Stanley:

This letter and the attachments are in response to your March 6, 2007 letter requesting that we address your comments to continue the review process.

1. Full size site drawings by a licensed engineer are being completed by Charlie Weaver, PE, Orion Engineering, 610-B Minuet Lane, Suite 118, Charlotte, NC 28217 Telephone: 704 523-1707. They will be forwarded to you by separate cover direct from the engineer.

2. Interior layout of building and equipment will be provided by the same engineer as #1

3. Specifications for the BondTech Autoclave is attached

4. The interior layout, #2, will show the future location for the second autoclave. Only one unit is going to be installed at the start up.

5. We will show in drawings the location of the reusable cart wash. It is not automated, in that containers are manually placed on a conveyor that takes the container through a tunnel washer, and then they are manually unloaded and stacked to dry. The automated sharps washer is a different piece of equipment and will not be installed at the time of start up. I suggest that modifications in the layout to accommodate the sharps washer be addressed at a latter date. This is not part of the operation that requires a permit in any case.

6. The building is not owned by BMWNC, and a copy of the owner's certification which you sent me is attached.

7. As all waste received is treated within the 7 day period allowed from point of generation, we do not plan to install refrigerated storage or provide for refrigerated trailers for storage. As with our incinerator treatment plant in Matthews, we have been able to comply with the seven day rule.

8. In response to the variance from the parameters prescribed in Rule .1207(2)(a), we can offer the following for our rationale for 30 minutes at 275 degrees F.

a. BMWNC utilizes pre and post vacuum cycles, which significantly enhances steam penetration during the heat cycle,

b. These parameters comply with other state parameters, such as NY, where the NYDEC has done field testing to prove effective log 6 kill results.

c. We have operated this type of autoclave, (gravity feed, pre vacuum, post vacuum, 275 degree F operating temperature, 30 minute residence time at temperature), for over 20 years in 5 different RMW treatment facilities and with the same manufacture's autoclave equipment. We have done challenge testing, i.e. tests on start up, and frequency of tests from every 40 hours of operation to once a month, and we have yet to have a failure.

d. The test results have been reviewed by the appropriate regulatory inspectors in Colorado, Kansas, Kentucky, Michigan, New York, Pennsylvania, and Utah during a period of several years and no violations or exceptions have occurred.

e. Testing under the proposed operating conditions is planned at start up, using non infectious test materials and containers, as closely resembling normal RMW to be treated at the site, using the procedure attached. Thus, the treated waste can be disposed without restrictions. Thereafter, we plan to test RMW daily for 30 days, then weekly for the next 90 days, and then monthly thereafter.

f. As the glass vial used to test effective disinfection changes color if heated sufficiently to kill the pathogen used, a failure can be spotted on the spot, without waiting for the incubation cycle, (usually 3 days). Any waste not passing the test would be as yet unloaded, or at worst, in our compactor, located on site, should a rerun be justified.

Test procedures are attached.

9. Unit capacity of an autoclave is volume rather than weight limited. The autoclave capacities listed equates to 84 Tons per day. We requested 90 tons per day so as to not be limited by variations in lbs per foot of RMW received in any one day. As transfer of RMW is not regulated, the maximum amount estimated of 96 Tons per day is simply a guess at the maximum that we could envision being transferred. In reality, it is much less, but the facility can accomplish this much with the room and equipment shown in the drawings, #2 above.

10. Transfer or treated waste will comply with the regulations. We are hereby amending the reference in the operating plan Section 3.2.21 to that shown below. Advise if this is satisfactory. The sentence that you refer to is amended to read:

    a. The maximum time that this transfer trailer can be stored on the yard will be limited so that NC regulations can be followed, which includes the time for transport from the generator, transfer and then transport to the treatment facility being used is seven (7) days.

11. The last sentence of the Operating Plan Section 3.2.34 shall be amended as follows:

    a. Storage times at the transfer station for untreated regulated waste will not exceed seven (7) days from shipment from the generator, transfer, and then transport to the treatment facility without refrigeration.

To keep this process moving along crisply, I will have the engineer send the drawings, #1 and #2 above, directly to you. I have attached a modified Operating Plan, based on the comments above.

Sincerely,

David J. Schoonmaker
President

Attachments:

1. Manufacture's specifications on the autoclave. (We are no longer considering the alternate chemical treatment technology, so that specification is not attached.)
2. Testing protocol for challenge testing of the autoclave

Attachment 1 – Autoclave Specifications

1.1.0 *BONDTECH* AUTOCLAVE/STERILIZER SYSTEM SPECIFICATIONS

High vacuum/High pressure, Computer controlled, Bondtech autoclave system to treat biomedical waste on-site

1.1.1 AUTOCLAVE DIMENSIONS AND CAPACITY

Size:	6' dia x 20' long
Number of bins:	4/load
Cycle time:	45 minutes

1.1.2 AUTOCLAVE VESSEL SPECIFICATIONS

Working Pressure:	75 psig
Safety Relief Set Point:	55 psig
Opening Assembly:	Single door/quick opening door/safety pin interlock
Loading Arrangement:	Horizontal
Pressure Vent:	Spray condenser

1.1.3 INSULATION

The exterior of the autoclave will be insulated with 2" of fiberglass, which will be covered with an aluminum jacket to protect the insulation, and to make sure the equipment can be kept clean.

1.1.4 PROCESS VALVES

Complete with the process valves including steam supply, pressure vent and safety relief.

The steam inlet valve is a ***high-resolution pneumatic proportional valve for a smooth accurate control of steam pressure.*** For safety, the steam inlet valve is a normally closed valve that closes in the event of any power loss.

1.1.5 AUTOCLAVE VESSEL DESIGN

The autoclave vessel is designed, fabricated, tested and certified in accordance with the ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, for Unfired Pressure Vessels. The vessel is designed for full vacuum. The sterilization unit is formed and welded into a horizontal cylindrical

pressure vessel with a hydraulic quick opening door. The vessel includes two rigid support saddles to facilitate a simple installation. The front face of the vessel has a machine groove for the rigid high temperature seal gasket.

1.1.6 VACUUM SYSTEM.

Vacuum System: Vacuum: 24-28" Hg.
High Efficiency Steam Ejector.

Vacuum Capability: 24"-28" Hg, 3 minutes maximum

Pre-vacuum: The pre-vacuum process will evacuate the autoclave 24"-28" Hg. This process will achieve the removal of air from the autoclave to provide a quick and efficient penetration of steam throughout the medical waste load.

Post-vacuum: The post-vacuum process removes excess steam from the vessel and expedites the steam purging process. This process removes excess moisture from waste load resulting in a lighter/drier treated waste product for disposal. Moisture removal effectively controls nuisance odors.

1.1.7 STEAM CONDENSER

Independent steam condenser manufactured of pressure-grade steel. The condenser is designed for quick and efficient steam purge from the autoclave vessel. Process steam is fully condensed externally to the autoclave vessel. ***Steam purge process is completed within approx 2-3 minutes.***

1.1.8 DOOR OPERATION, SEALING AND LOCKING MECHANISM

The door is hinged mounted on the autoclave. Mounting arrangements to provide full movement to a full open position. Preferred sealing system to utilize one-piece extruded material O-ring seal type. The door has a positive lock type safety design per the ASME requirements. The locking mechanism is interlocked with the control system to prevent opening the door while under pressure, and to prevent pressurization when the door is unlocked. The door is designed with several safety features that include electric/mechanical interlock switch, PLC interlock, door safety handle interlock, visual site gauge for pressure monitor and analog dial pressure/temperature indicators.

1.1.9 MATERIAL HANDLING – LIFT TABLE

The Lift Table is an automatic/hydraulic operation. Tracks are provided at the bottom of the autoclave to match the autoclave waste bins.

1.1.10 SYSTEM PIPING.

The autoclave system will completely piped at the factory prior to shipment for simple installation. The system piping will consist of the following:

- Steam condenser piping – steam outlet piping direct to steam condenser. Steam is condensed by controlling water flow through the steam condenser with respect to steam pressure inside the vessel. The water flow control minimizes the consumption of water.
- Condensate Drains Steam traps (2) – front and rear steam traps maintains the vessel free of condensate.
- Vacuum Valve/Piping – autoclave is hard piped to either steam ejector or vacuum pump for integrating vacuum system to vessel.
- Steam Inlet Valve/Strainer – proportionally controlled steam inlet valve for smooth and accurate control of steam pressure inlet. Steam inlet valve is controlled by a PID loop controlled by the PLC.

1.1.11 CONTROL SYSTEM/PROCESS VALVES/CONTROL PANEL & INSTRUMENTATION

The autoclave control panel is package in a NEMA 12 rated panel. The autoclave system is controlled by a state-of-the-art "SuperMicro" Programmable Logic Controller (PLC) with modem hookup capabilities for online support. The PLC performs automatic sterilization control control that includes pre-vacuum, pressurization/heat soak, vent and post-vacuum. The PLC monitors pressure vessel conditions for providing safety interlock for door operation.

1.1.12.1 SUPERMICRO PROGRAMMABLE LOGIC CONTROLLER (PLC).

The FX2N Series PLC provides the function controls that automatically commands the process cycle steps for the autoclave system. Extensive data memory (over 8,000 Data Registers) for capturing real time operating parameters that continuously monitors autoclave system performance.

The FX2N Series PLC support on-line troubleshooting/programming functions, used in system development and commissioning. Remote programming/monitoring capability by modem provides for immediate technician support. This PLC system has the external data link integration capability for communication with other peripheral systems (PC, network, control systems, etc).

Powerful features include:
- Windows Programming - Use Ladder, List or SFC languages.
- Operator Interfaces – Flexible selection to match specific customer application
- Extensive Program Memory – 8,000/16,000 steps
- Extensive Data Memory – 8000 Data Registers
- Enhanced Program Throughput – 80 nanoseconds/step
- Enhanced Process Control – Auto-Tuning, PID loop
- High-Speed Processing–60KHz counters, 10ms timed&50us hardware interrupts
- Embedded Motion Control – 20,000 hz pulse train, Trapezoidal ramp instructions
- High Function Math – 32 bit floating point, Square Root, Trigonometry
- Year 2000 Compliant – Y2K Compliant, 4 digit year
- Real Time Clock/Date – For scheduling date and time stamping
- Flexible Configurations – From 16 to 256 I/O & extensive special function I/O capabilities
- Communications – Built-in 2nd port (RS-232/RS422/RS485) & PLC-PLC networking
- Open Network Connectivity – Modules for Profibus DP, Profibus DP I/O, AS-I & CC Link

1.1.12.2 SYSTEM PROGRAMMING

PLC program application is based on the industry standard ladder logic. Programming can be performed by authorized personnel with access to system entry code.

Simple pushbutton entry pad allows the authorized personnel to enter specific parameters including the following:

- Pre-Vacuum Set Point
- Pre-Vacuum Timer
- Sterilization Temperature/Pressure
- Sterilization Heat Soak Time
- Vent Time Set Control
- Post-Vacuum Set Point
- Post-Vacuum Timer

In addition to the above, specific alarms are setup for triggering equipment shutdown and notifying the operator in the event that temperature and/or pressure parameters are not satisfied.

1.1.13 CONTROL SYSTEM PRINTER
-OR- Honeywell Circular Chart Recorder

The control system printer is a state of the art Honeywell printer. The DPR series printer generates continuous data that provides the history of every autoclave cycle. The 100 mm (4 inch) is a multi-pen recorder with high functionality.

The DPR series printer will record and generate chart data that includes the following:
- Time and Date of every autoclave cycle.
- Cycle Start and Cycle End Time.
- Continuous Cycle Vacuum & Pressure
- Continuous Cycle Temperature

Some of the powerful features for the Control System Printer:
- 100 mm (4 inch) chart width
- 0.1% accuracy full scale (IEC 873)
- Each input span has an adjustable selected range
- Universal input board (T/C, RTD, mV, mA, volts
- Alphanumeric Display: 12 digits or 1 or 2 bargraphs, adjustable brightness
- Roll or fan fold chart
- Fully documented chart with trace color assignment
- Alarm trend, tagging, zoning, trend/tabular print outs, all at up to 500 mm/h (20 in/h)
- Up to six analog inputs can be configured on a 3-pen printer
- Full configurabilitiy through front keys & interactive menu with multi-password capability
- 4 lines batch header automatically incremented and saved in case of power failure
- 12 alarm set points, assignable to any input, math result, communication signal
- Easy Access to Chart and Ink cartridges is straightforward, reducing maintenance costs.

2.0 AUTOCLAVE CONVEYOR SYSTEM.

- Optional Internal Conveyor System w/ Integrated Lift Table.
- Conveyor -- 30" Chain Centers X 20'long
- Chain -RC60S on ½" square steel guide rail (Stainless Chain – Tsubaki Carbon steel option)
- Includes Electrical Drive System – Externally mounted (outside of autoclave)
- Conveyor Chain Speed – 30 fpm
- Conveyor Metaline Brand flange bearings rated at 800 F.
- Autoclave Penetration and Flanges to accommodate conveyor drive assembly installation.
- Autoclave flange & seal system integrated into conveyor drive assembly.
- Conveyor Installed & Aligned inside autoclave
- Hydraulic Lift Table w/ CDLR conveyor mounted (~ 8' long X 54" wide)
- Hydraulic Lift Table – 4,000 lift capacity
- Hydraulic Lift Table – Conveyor Speed – 30 fpm.
- Conveyor & Lift Table Controls interlocks integrated into BTT control system.
- BTT PLC program mod to include Conveyor & Lift Table logic.

3.0 Start-up/Testing/Training.

The Bondtech start-up supervision will include the following:

Bondtech Start-up supervision, Operator Training & Equipment Documentation.

Bondtech will conduct classroom and "hands-on" training sessions. The Bondtech training program will focus: 1. Safe Operation, 2. Compliance & 3. System Maintenance. Bondtech will provide a comprehensive training program that includes the following.

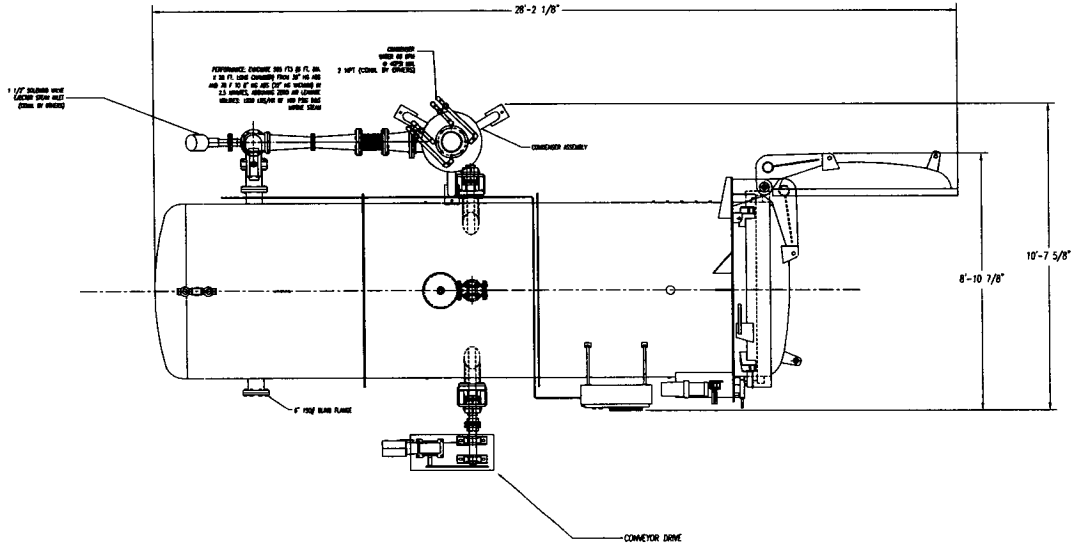
a. Bondtech SOP. Bondtech will develop a Standard Operation Procedure (SOP) specific for customer's operation. The SOP will address compliance with State Environmental Agency's medical waste treatment regulations.

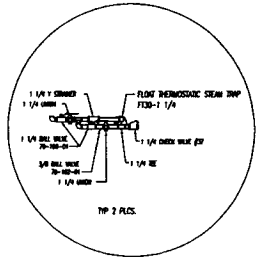
b. Bondtech Personnel Classroom Training. Bondtech will perform a classroom type training session. Personnel will receive his/her own copy of the Bondtech medical waste sterilization SOP. After the classroom training is completed, all trained personnel will execute a SOP Training Certification Form.

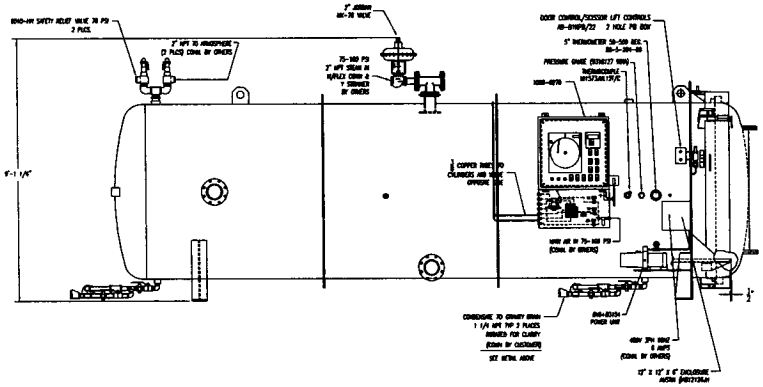
c. Bondtech Equipment Operation Training. After the classroom SOP training, Bondtech will conduct a comprehensive equipment operation & maintenance "hands-on" training session.

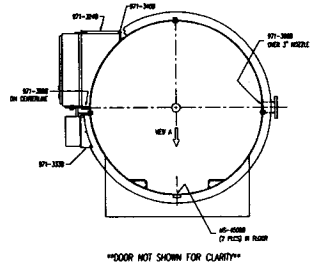
d. Bondtech Operation and Maintenance Manuals.
Bondtech will provide two copies (three ring binders) of the Bondtech Operation and Maintenance (O&M) manuals. The O&M manuals will include complete installation drawings, parts/components properly identified and electrical/control wiring schematics.

BILL OF MATERIALS				
ITEM	QTY	DESCRIPTION	DWG/PART NO.	VENDER
#	#	Description	x	x









REV	DATE	REVISION DESCRIPTION	BY	CHK
-	-			

UNLESS OTHERWISE INDICATED, TOLERANCES:
X.X = ± 0.025 ANGLES ± 1 DEG.
X.XX = ± 0.010 FRACTIONS ± 1/64
X.XXX = ± 0.005

DO NOT SCALE
BREAK ALL SHARP EDGES
REPORT ALL ERRORS TO ENGINEERING DEPT.

MATERIAL	NO. REQ'D
	1

BONDTECH CORPORATION 3400 N. HWY 27 SOMERSET, KY 42501 USA

DRN. RSL	DATE: 3/05/07
CHK.	APP. SCALE: NONE

BTT 6' X 20' AUTOCLAVE
HEALTHCARE GASTONIA, NC

NO. HEALTHCARE BTT6020 GA 030507 REV. 0

Efficacy Testing Protocol

Prior to Commencement of Operations

1. Boxes and bags will be assembled to closely represent regulated medical waste. Boxes will be approximately 4.5 to 6 cubic feet, filled with sterile gowns, sharp containers, tubes, Petri dishes, glass vials, fluid canisters, each weighing 25 to 50 lbs. The autoclave bins will be loaded so that the total net weight of test waste will be approximately 3,500 lbs.

2. A biological indicator, using *Bacillus stearothermophilus* or a dual spore test using *Bacillus stearothermophilus* and *Bacillus subtilis var. niger)* along with a specially formulated soybean casein digest growth medium will be placed in multiple locations, a minimum of ten sites, inside of the boxes or bags, near to the center of each container. This is a commercial test product manufactured by 3M or equivalent.

3. The autoclave will be put through a cycle, which includes:

    a. Load autoclave bins into the autoclave and shut door. Start the automatic cycle.
    b. Pre Vacuum for 3 minute (18-20" Hg)
    c. Steam injection unit the unit temperature reaches 275 degrees F
    d. Soak time for 30 minutes
    e. Exhaust steam through a condenser
    f. Post Vacuum for 3 minutes
    g. Equalize atmospheric and vessel pressure, open door

4. Recover the biological indicator, note color change, then incubate per manufacture's instructions, and complete a report. Send copy to NCDENR

Commence Operations

1. Log the operation in an operating manual, including estimated weight, date and time
2. Before loading bin, using a vial holder on a wood rod, place a vial in the center of a load once each day, for the first week and log the results on color change and incubation results.
3. After the first week, if there are no failures, this test would be conducted once a week for the next twelve weeks.
4. If there are no failures, this test would be performed and logged once every month.
5. In the event of a failure, tests would be conducted on every load for the next month, and then start on step #2 and go through step #4 herein.
6. A continuous log will be kept on all cycles, including time, pressure and temperature for the treatment process. These logs to be kept on site for inspection in compliance with NC regulations in the Operating Plan

BMWNC, Inc.
Steam Sterilization Facility
Gastonia, North Carolina

OPERATIONS PLAN

Date: January 18, 2006

1.0 **INTRODUCTION** BMWNC, Inc., (a wholly owned subsidiary of Healthcare Waste Solutions, Inc. which owns and operates five autoclave facilities, one incinerator, and five transfer stations for medical waste), plans to build and operate an autoclave plant at 148 Boxwood Lane, Gastonia, NC. The site, consisting of a 10,640 square foot warehouse on approximately two acres is properly zoned (zoning letter attached) and suited for medical waste treatment, transfer of medical waste for appropriate treatment off site, for handling reusable sharps containers, transportation of untreated and treated medical waste. The facility can house either two (2) steam sterilization units (autoclave) or two (2) chemical treatment units. Treated waste will be compacted into roll offs prior to being transported to a permitted Sub-Title D Landfill, municipal or waste to energy incinerator, to other properly permitted medical waste treatment facilities. The operating parameters for waste treatment are detailed in this Operating Plan, with applicable requirements set forth in the NC GS 130A-294 solid waste management program and including 15A NCAC 13B, (.1200, .1201(e), .1201(4) .1202, .1203,.1205, 1206, 1207(1), (2) and (4), and .1207(1))

2.0 **Facility Identification** BMWNC, Inc., 148 Boxwood Lane, Gastonia, NC, Federal ID# 56-1934817 , Mailing Address: 3212 Campus Ridge Rd., Mathews, NC 28105, Attn: Norman Martin, Plant Manager.

3.0 **Operations:** The facility is operated in accordance with rules and regulations set forth by the division of Waste Management, North Carolina and the City of Gastonia, NC. The manufacture's Operating Manuals are kept on file at the Plant Manager's office. All employees, based on job description, shall receive training as to the contents of the manual, safety procedures and practices, operation, maintenance, OSHA rules, including lock out, tag out and Bloodbourne Pathogens, servicing and maintenance of the equipment and safety practices. BMWNC, Inc. accepts prepackaged boxes, reusable and disposable containers of various sizes containing medical waste, sharps in containers or reusable containers, pharmaceutical waste from generators, BMWNC owned and operated transportation equipment, and roll offs and vans from third party licensed haulers and transporters. Wastes requiring incineration will be transferred to BMWNC's incinerator at Matthews, NC or other properly permitted incinerators capable of treating by pass waste. The accepted waste is treated by steam sterilization units, (autoclave) or by chemical treatment. Treated waste would then be disposed of at a Sub-Title D landfill or, if available, at a municipal or waste to energy incinerator.

3.1 **General Operations:** Waste is transported to the treatment plant from generators by way of BMWNC drivers or licensed Transporters with whom BMWNC contracts treatment services. It is received in DOT approved corrugated boxes, reusable and other disposable containers, roll off containers and sharps transporters. The containers are offloaded at the truck docks or the bay door. All waste received shall be manifested and the customer and generator recorded as required by NC regulations. Upon receipt, containers are recorded as to weight, type of container and number of containers. Any waste requiring incineration or transfer is trans-loaded into a trailer or truck and sent to BMWNC's Matthews, NC or other properly licensed and permitted incinerator or treatment facility. Personnel will use hand trucks, forklifts or conveyors to unload or transfer medical waste. Once accepted, the waste is loaded into treatment bins and treated in one of the sterilizers or chemical units. After treatment the waste is compacted into a roll off container for shipment to a permitted disposal facility.

3.2 **Detailed Operations**

3.2.1 The sterilization or chemical treatment units are PLC controlled and utilize paper recorders that record cycle times, temperature, pressure, or chemical additions, pH and other parameters to demonstrate treatment efficacy.

3.2.2 BMWNC, Inc. provides collection and/or treatment services to the health care industry in the states of VA, WV, TN, GA, NC, SC, DC, MD, FL and KY. The service, if done directly with the generator, includes supplies, boxes or containers, reusable sharps containers, and the like, with labels, manifests, barcodes and eventually radio chips for tracking, customer identification, and other DOT requirements. For other collection companies, the facility would receive, log, treat or reship, wash containers, and provide other services needed to meet the healthcare needs in the region and/or the licensed transporter.

3.2.3 Medical waste will be transported in trucks and/or trailers by employees of BMWNC, or by licensed Transporters. Medical waste is shipped to the facility in approved corrugated boxes, reusable containers, roll offs, disposable containers and in sharps transporters that meet DOT requirements. BMWNC does not transport, accept, treat or transfer medical wastes that are not properly packaged or classified in accordance with 15A NCAC 13B, section .1204.

3.2.4 BMWNC shall also maintain compliance with the requirements of section 15A NCAC 13B.1205, which includes:

3.2.4.1 Rejection of waste that is improperly packaged

3.2.4.2 Medical waste shall be transported in a manner that prevents leakage of contents of the package

3.2.4.3 The integrity of the package shall be maintained at all times

3.2.4.4 The labeling and marking of the package shall be maintained at all times.

3.2.4.5 All loads containing medical waste shall be covered during transportation

3.2.4.6 The universal biohazard symbol shall be displayed on all transportation vehicles, in accordance with the US DOT standards and 49CFR 172 Subpart F.

3.2.4.7 Medical waste, both that is treated on site, or that transferred, shall be treated or delivered to a permitted storage or treatment facility within seven calendar days of the date of receipt from the generator.

3.2.4.8 If longer storage than seven (7) days is ever required, it shall be refrigerated at temperatures between 35 and 45 degrees Fahrenheit and shall be maintained at these temperatures until treated or transferred.

3.2.4.9 A contingency plan shall be prepared and maintained in each vehicle, as well as a emergency response kit, used to transport medical waste. The operator of each vehicle shall be knowledgeable of the plan and use of the kit.

3.2.4.10 Vehicles used for the transportation of 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.

3.2.4.11 While transporting medical waste, vehicles are prohibited from transporting any material other than solid waste and supplies related to the handling of medical waste.

3.2.5 The medical waste containers are offloaded at the dock by hand truck, forklift or conveyors, or by rolling them off if the container has wheels, (such as sharps transporters, larger reusable plastic containers) by employees. Thus, containers shall remain intact from the generator's site during treatment and up to and until transfer or treatment. Containers shall not be compacted before transfer or treatment. All reusable containers shall be constructed or smooth and easily cleanable materials.

3.2.6 Properly classified medical waste that cannot be treated by a sterilizer or chemical treatment process are segregated and staged for further transport to a licensed and appropriate treatment facility, most often to BMWNC's incinerator in Matthews. Shipping documents are utilized to track this material to the proper treatment and disposal facility. No waste shall be accepted that does not meet the packaging requirements of 15A NCAC 13B .1204.

3.2.7 All containers that have been scanned, recorded, and weighed are conveyed to a dumping platform or hydraulic tipper/dumper. Disposable and/or the contents of the reusable containers are then dumped into the treatment bins, or in the case of a chemical

treatment unit, into the treatment chamber itself. After dumping, the reusable containers are conveyed to a container washer where they are cleaned with hot water and a disinfectant. The dumping process is repeated until the treatment bins or chamber are full or until they have the proper weight in them for loading into either the sterilizer(s) or chemical treatment units (2) for treatment.

3.2.8 In the case of a sterilizer, once the treatment bins are filled with untreated medical waste, the bins are conveyed via forklift to a staging position. Treatment bins are then loaded into the autoclave by placing them on a scissor lift that had rollers or chains to load them into the autoclave. Unloading of treated waste in treatment bins is done the same way, after which they are staged to be dumped into a compactor that feeds directly into a compactor vessel for shipment to an approved landfill or, if available, to a waste to energy incinerator. Once emptied, the bins are available again for refill with untreated medical waste.

3.2.9 In the case of reusable sharps, the sharps containers are unloaded from a transporter, are then loaded on a automated sharps washer, which opens the container, empties the contents into a treatment bin or reusable tub, and then washes the container, after which they are detailed and loaded back into transporter carts. Once the bin or container used to receive contents if full, they are moved to the sterilizer or chemical treatment unit, and the contents are treated the same as other medical waste.

3.2.10 In the case of a chemical treatment unit, the waste is loaded into the unit, the automatic cycle is run, and after treatment is loaded into a treatment bin and staged for compaction and loading into a compactor vessel for transport to an approved landfill or alternate waste to energy incinerator.

3.2.11 BMWNC will either use up to two (2) National Board and NC Department of Labor approved pressure vessels or approved chemical treatment units. (The choice of technologies will be confirmed with the appropriate NC agencies once a decision is made on the choice of these two approved technologies.) In the case of an autoclave, the vessel will be constructed of carbon and stainless steel, are 8' in diameter, and 32 feet long, each holding up to six coated bins for easy handling, dumping and reuse. The autoclave is fed steam provided by a 250 hp fire tube boiler that is National Board and NC Department of Labor approved.

3.2.12 Once either the autoclave or chemical treatment unit is loaded, the door is closed, the process is controlled by a PLC unit. Autoclave units will go through three cycles, first a pre vacuum stage to evacuate ambient air, then steam injection of steam to reach and maintain a temperature of 275 degrees or higher at up to 80 PSI. The equipment shall have a gauge to measure pressure on each cycle. When the temperature in the autoclave is reached, the waste

is treated for 30 minutes at 275 degrees or higher, to achieve efficient pathogen kill at the core of the load. When complete, the steam pressure is released through a condenser that reduces steam release to the atmosphere, and then a second vacuum is applied, which reduces steam condensate and odor in the building. Once done, an alarm alerts employees to unload the autoclave. For a chemical treatment unit, the cycle time is 15 minutes, which has proven efficacy data, and again the unit is unloaded into treatment bins for dumping at the compactor.

3.2.13 Efficacy of both the sterilization process and the chemical treatment is confirmed at least once per week (as per section .1207(2)(d)) using a dual species (Bacillus Atrophaeus and Geobacillus Stearothermophilus) biological indicator. Also used in the sterilization cycle only is a heat sensitive indicator strip to determine kill efficiency.

3.2.14 Both systems log each cycle on a continuous chart recording system, showing time, temperature, and pressure for the sterilizer, and time, chemical addition, pH and temperature for the chemical system. Data will be retained on file for three (3) years.

3.2.15 The bins are picked up by forklift and emptied into a hopper on the compactor. When emptied, they are staged for reloading of medical waste.

3.2.16 Emergency shutdown buttons on located on each piece of treatment equipment, both types on the control panel.

3.2.17 Treated materials are then transported, based on the requirements of the permitted landfill or waste to energy incinerator. BMWNC anticipates using 20 to 25 foot compactor vessels for transport on a roll off truck, both supplied by the landfill or incinerator. The units will have load cells to prevent overloading.

3.2.18 Operator training shall comply with DOT, OSHA and NC Department of Labor and Solid Waste regulations. This includes training on the equipment, process, lock out/tag out, regulations that apply to the permit and process, and safety. Frequency includes training upon being hired, and then periodic refresher courses as required in the applicable regulations and by company policy.

3.2.19 Maintenance of equipment will use the maintenance inspection frequency, service, replacement of parts, and other requirements recommended by the manufacturer of the key equipment and verified using inspection sheets. Inspections will be on a daily, weekly, monthly or other schedule as recommended. Visual inspection of all equipment will be done daily to insure proper working conditions. Any equipment in need of repair or maintenance will be done when inspected or on a schedule, and non repairable equipment replaced. A schedule of maintenance

required will be posted at the plant and the tasks will be part of the training of employees.

3.2.20 On site traffic patterns include receipt of trucks or trailers, moving these to the loading dock when scheduled for processing or transfer, loading and then dispatch. All trailers or trucks with medical waste on board will be kept locked on the yard. Storage logs will be kept to insure that waste is treated within seven (7) days or, if refrigerated as noted above, for no longer than the requisite number of days.

3.2.21 Loading and unloading will be scheduled by the dispatcher. Upon arrival at the facility, the manifests that accompany each load, (the number of manifests vary by the number of generators' containers in the truck/trailer) and other paperwork is delivered by the driver to the dispatcher or plant supervisor. The load is logged in with time and date. If available, the load is placed at the dock for treatment of the medical waste, or assigned a parking space for later unloading and treatment. Medical waste requiring incineration or other off site treatment will be staged and loaded into a trailer for transport. The maximum time that this transfer trailer can be stored on the yard will be limited so that NC regulations can be followed, which includes the time for transport from the generator, transfer and then transport to the treatment facility being used is seven (7) days. The transfer truck will be cleaned/disinfected when visibly soiled or otherwise immediately in response to a spill or leakage using the onboard spill kit and disinfectant.

3.2.22 When BMWNC collects medical waste, all personnel in contact with containers will ensure that 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. Inspection of containers offered for shipment will verify:

3.2.22.1 Each container is properly sealed and taped (boxes) as per requirements of 15A NCAC 13B.1204 before transport,

3.2.22.2 Each container must not be damaged (crushed, cut, bent or leaking),

3.2.22.3 Each container must be in an upright position

3.2.22.4 Any improperly packaged containers will be reported to the customer for repackaging. BMWNC employees will not assist in the packing procedures.

3.2.22.5 Once inspected and loaded, the driver will transport them to the vehicle in a manner that will not damage or tip the container and shall deliver them within seven (7) days of the shipment from the generator.

3.2.22.6 The container is marked or labeled so that the generator's name, address and telephone number, transporter's name, address and telephone number, treatment facility's name, address and telephone number, date of shipment and "INFECTIOUS WASTE" OR "MEDICAL WASTE" and the BioHazard symbol, (in accordance with the DOT standards and 49 CFR172 Subpart F), is visible on the outer surface of the container. The bar code can contain this information or the boxes must be so labeled.

3.2.22.7 The manifest shall include the amount of waste by number of packages, date shipped off site, name of the transporter and the name of the treatment facility. This shall become part of the record and be kept on file at the treatment plant for three (3) years.

3.2.22.8 A copy of this plan shall be kept at the treatment facility and maintained, including any amendments or modifications made here after.

3.2.23 Upon loading, the driver will complete the waste manifest, obtain an authorized customer representative signature and leave a copy with the customer.

3.2.24 Upon receipt and unloading, the operator will weigh each container and record its weight, if applicable using the bar code system, and note any discrepancies on the manifest or in the computer system to provide notes to customer service.

3.2.25 Any waste picked up for shipment, transferred or staged for transfer shall be stored in a manner that maintains the integrity of the packaging at all times and maintains the labeling and markings.

3.2.26 BMWNC processing facility can operate 24 hours a day, 7 days a week for treatment. Office hours will be Monday through Friday from 8:00 AM to 4:00 PM or extended hours as needed.

3.2.27 Access controls when the office or plant is not in operation will be accomplished through locked doors, alarms and the like, and the trucks in the yard will remain locked when parked for temporary storage. Only authorized personnel shall have access to areas of the facility where regulated medical waste is stored.

3.2.28 All areas used to store regulated medical waste shall be kept clean and no storage shall be permitted in areas where there is carpeting or floor coverings with seams. Vermin and insects shall be controlled.

3.2.29 All floor drains shall discharge directly to an approved sanitary sewage system. Ventilation shall be provided and shall discharge so as not to create nuisance odors.

3.2.30 This Operating plan shall serve as guidelines to ensure continued proper management of regulated medical waste.

3.2.31 Treatment volume limits are set based on the capacity of the autoclaves or chemical treatment equipment. The autoclaves can treat 3,500 lbs. per hour each, or 7,000 lbs. per hour and the chemical treatment equipment can treat 2,500 lbs. per hour each, or 5,000 lbs. per hour. The plant shall be limited to process no more than 96 tons per day and transfer up to 96 tons per day.

3.2.32 Records of regulated medical waste shall be kept at the facility by maintaining the manifest, but in addition, the facility shall record the weights received, number of packages on each manifest, date treated and the name and address of the ultimate disposal facility.

3.2.33 Storage of untreated waste shall be in a secure place, either within the locked building or in locked transport equipment. Storage of untreated and treated waste at the facility will be based in accordance with 15A NCAC 13B Sections .1206 and .1207(1). Treated waste is maintained either in bins or in the compactor vessel awaiting transport for final disposal. No more than 30 tons will be stored on the property at any one time.

3.2.34 Processed waste from the facility will be treated in the approved landfill or at a waste to energy incinerator. Untreated waste being transferred from the facility will be manifested to track the materials from the BMWNC treatment facility to an approved treatment facility, usually the BMWNC incinerator at Matthews, NC. Requirements of 15A NCAC 13B Sections .1206 (1) through (8) will be adhered to at all times when transfer of waste is required. Storage times at the transfer station for untreated regulated waste will not exceed seven (7) days from shipment from the generator, transfer, and then transport to the treatment facility without refrigeration.

3.2.35 In case of equipment failure or shut down, BMWNC will ship untreated waste to a permitted and approved facility, with a primary destination being the BMWNC incinerator at Matthews, NC. In such event, the requirements for storage and transport under 15A NCAC 13B will be maintained.

3.2.36 Employee Training is based on job description, responsibilities, and regulatory requirements under the NC Division of Solid Waste, NC Department of Labor, the EPA, DOT, and OSHA

3.2.36.1 Training will include, as applicable, company policies, Bloodborne Pathogens, Safety, Lock out/Tag out, Hazard Communication, DOT hours of service, OSHA and EPA regulation training, Personal Protective Equipment, accident and injury reporting, Access to Exposure and Medial Records Materials, substance abuse and alcohol misuse, proper lifting methods, entry into confined spaces, DOT Hazmat, and driver training.

3.2.36.2 Specific training will apply to operators of the autoclave sterilizer or chemical treatment equipment, the

reusable sharps washing system and containers, the tub washing station, and other equipment as required by the manufacturer and NC Permit requirements.

3.2.37 Record keeping shall include daily logs and time and temperature charts, plant operations weekly reports and production summaries, statistical reports, monthly maintenance report, volumes received by country and state, logs of transferred materials and sites where transferred, log of disposal of treated waste, spill reports and accident reports.

3.2.38 Volume reports to NC – on or before August 1st of each year, BMWNC shall report the amount of waste received (in tons), amounts transferred, amounts treated to the NC Solid Waste Section on forms prescribed by the Section. It shall include wastes handled from July 1 to June 30th of the previous 12 months, the amounts received, treated or transferred in tons on a monthly basis and a copy of the report sent to the County Manager from which waste was received.

3.2.39 Steam sterilization shall not be employed for pathological waste and for chemical treatment conducted at BMWNC, (unless specific approval is granted based on the chemical treatment equipment and testing data submitted at a later date).