

Thursday, August 18, 2016

Attention: Larry Frost
NC DEQ, Division of Waste Mgt.
Solid Waste Section Permitting
2090 US Highway 70
Swannanoa, NC 28778

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Regulated Medical Waste Processing & Treatment Permit Application for:
Daniels Sharpsmart, Inc.
1851 Chespark Dr.
Gastonia, NC 28052

Fac/Perm/Co ID #	Date	Doc ID#
3617	8/23/16	26677

APPROVED DOCUMENT
Division of Waste Management
Solid Waste Section

Corporate Address:
Daniels Sharpsmart, Inc.
11 West Jackson Blvd. Suite 720
Chicago, IL 60604

Date August 30, 2016 By

Larry Frost
Digitally signed by Larry Frost
DN: cn=Larry Frost, o=Division of Waste Management, ou=Solid Waste Section, email=larry.frost@ncdenr.gov, c=US
Date: 2016.08.30 12:49:33 -0400

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Division of Waste Management
Solid Waste Section
Date August 30, 2016 By


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SOLID WASTE SECTION
ASHEVILLE REGIONAL OFFICE

**Regulated Medical Waste Processing & Treatment Facility for
1851 Chespark Drive Gastonia, NC 28052**

Thursday August 18, 2016

The following information has been prepared in accordance with North Carolina Administrative Code 15A NCAC 13B .1207 (1) & (2) for Daniels Sharpsmart, Inc. 1851 Chespark Drive Gastonia, NC 28052. This operations plan will be prepared, maintained and updated as necessary to ensure continued proper management of Regulated medical waste at the facility. This written plan will also be maintained at the facility and units of the facility as necessary to ensure consistent procedures are used to manage regulated medical waste.

The facility must also keep a copy of the permit, operations plan, and site drawings on site at all times.

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**SOLID WASTE SECTION
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Section I

General Information

The North Carolina Medical Waste Rules cover all aspects of medical waste management including: packaging, storage, transportation, treatment and disposal. The application and operations plan has been prepared to satisfy the requirements in NCDENR 15A NCAC 13B. [.1200](#) for operation of an off-site Regulated Medical Waste Treatment and Processing Facility. Medical waste is regulated as solid waste and not as hazardous waste.

Medical waste is also subject to all general requirements for solid waste found in the [solid waste management regulations](#). The NC medical waste management regulations are administered by the North Carolina Department of Environment and Natural Resources, Division of Waste Management.

Name of Proposed Facility

Daniels Sharpsmart, Inc., 1851 Chespark Dr. Gastonia, NC 28052

Name, address, telephone number, and email address of the applicant and contact person.

Kyle Little; 111 West Jackson Blvd. Suite 720 Chicago, IL 60604; 312 – 285 – 9087; KLittle@DanielsHealth.com

Name, address, telephone number, and email address of the contract operator and contact person, if applicable.

Not applicable.

Name, address, telephone number, and email address of the landowner. A landowner authorization form must be signed and notarized if the property is to be leased (see attached form).

Grantee – Daniels Chespark NC, LLC, A Delaware Limited Liability Company.

111 West Jackson Blvd. Suite 720 Chicago, IL 60604

Name, address, telephone number, and email address of the engineer, if applicable.

NA

Name, address, telephone number, and email address of person to receive permit fee invoices and annual fee invoices.

Kyle Little; 111 West Jackson Blvd. Suite 720 Chicago, IL 60604; 312 – 285 – 9087; KLittle@DanielsHealth.com

Section II

Property Information and Maps

Describe the location of the facility. If the property was previously used for solid waste management activities, provide a description of the operation including permit information and a map with boundaries.

The location of the facility is located at 1851 Chespark Drive Gastonia, NC 28052. The facility is within the City of Gastonia's Planning Jurisdiction and located within the I – 2 Exclusive Industrial Zoning District. The use, "Manufactured Goods, Class I", is allowed by right within the I – 2 Zoning District. The purpose occupancy of the subject property by Daniels Sharpsmart, Inc. for the purposes of the collection, device management, and treatment of medical waste.

Latitude (North): 35.2884000 - 35° 17' 18.24"
Longitude (West): 81.2197000 - 81° 13' 10.92"
Universal Transverse Mercator: Zone 17
UTM X (Meters): 480022.1
UTM Y (Meters): 3904850.0
Elevation: 762 ft. above sea level

The City Directory Image Report was reviewed, which included directories dating from 1987 to 2013 for properties located on Chespark Drive and Sparta Court. The subject property was listed as MA Hanna Color in 1999, Poly One in 2003, Gutter Guardian in 2008 and Cynergy Systems Inc. Construction in 2013.

The city directories for the adjacent properties were also reviewed. The property to the northwest (1708 Sparta Ct) was listed as Recore Electrical Contractors, Inc. from 1995 to 2013 Properties to the east and west are undeveloped and not listed in the city directories. A copy of the EDR City Directory Image Report is provided as **Appendix B**. The property was not previously used for Solid Waste Management.

Based upon the historical information obtained and reviewed, the subject site was farmland from prior to 1956 to 1998. A commercial/industrial building was constructed on the subject property in 1994. The structure is similar to the one observed at the time of the site reconnaissance. From prior to 1956, properties immediately surrounding the subject site were wooded and/or agricultural with scattered rural residences. Between 1993 and 2005, commercial development occurred to the north, west and east of the site.

Provide the total acreage of the property and the size of the actual area to be used for the facility and storage operation.

The total acreage of the property is 5.4 acres + / - .

Daniels current facility space will be a total of 13,584 square feet with an estimated 3,000 square feet designated for storage. Daniels will expand into additional areas of the building and may occupy up to 28,584 sq. feet +. Closure costs for the facility are currently estimated using the additional and potential floor space.

Provide a legal description of the property and a complete copy of the land deed.

Appendix A - Tax parcel number of the Property is: 135942, and, Some or all of the Property, consisting of approximately 5.4 acres, is described in Deed Book 4641, Page No. 0939 Gaston County.

Provide a copy of the USGS topographic quadrangle map of the area. The property boundaries of the site and the approximate location of the building should be drawn onto the map. The map may be a high quality photocopy.

Appendix B

GRI utilized EDR historical topographic maps to review the subject site and surrounding area. A description of the site as shown on the maps is detailed below in chronological order. Copies of the topographic maps reviewed have been included as **Appendix B**.

Provide a letter from the appropriate City or County official confirming that the siting of the facility will be in conformance with all zoning and local laws, regulations, and ordinances, or that no such zoning, laws, regulations, or ordinances are applicable.

Appendix C

Section III

Introduction

Daniels Sharpsmart, Inc. has countless years of experience in Regulated Medical Waste Management with over 20 facilities operating in 40 states, in addition to a large global presence in countries including Australia, Canada, South Africa, and the United Kingdom.

Daniels is the world's largest provider of reusable systems for sharps disposal and the second largest company in the medical waste disposal industry in the United States. Daniels provides leading sharps and total waste solutions to the healthcare market. Daniels Sharpsmart, Inc. is proud to provide the safest, most environmentally friendly products and services to a wide variety of small, medium and large healthcare providers.

Daniels Sharpsmart, Inc. is proposing a Regulated Medical Waste Processing (Storage, Decanting and Washing - Washsmart), and treatment (Autoclave – Steam Sterilization) at 1851 Chespark Drive Gastonia, NC 28052.

Definitions

15A NCAC 13B .1201 Definitions

For the purpose of the Section, the following definitions apply:

"Blood and body fluids" means liquid blood, serum, plasma, other blood products, emulsified human tissue, spinal fluids, and pleural and peritoneal fluids. Dialysates are not blood or body fluids under this definition.

"Generating facility" means any facility where medical waste first becomes a waste, including but not limited to any medical or dental facility, funeral home, laboratory, veterinary hospital and blood bank.

"Integrated medical facility" means one or more health service facilities as defined in G.S. 131E-176(9b) that are: (a) located in a single county or two contiguous counties; (b) affiliated with a university medical school or that are under common ownership and control; and (c) serve a single service area.

"Medical waste" as defined in G.S. 130A-290(17a). Any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, but does not include any hazardous waste identified or listed pursuant to this Article, radioactive waste, household waste as defined in 40 Code of Federal Regulations § 261.4(b)(1) in effect on 1 July 1989, or those substances excluded from the definition of "solid waste" in this section.

"Microbiological waste" means cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial, and industrial laboratories.

"Microwave treatment" means treatment by microwave energy for sufficient time to render waste non-infectious.

"Off-site" means any site which is not "on-site".

"On-site" means the same or geographically contiguous property which may be divided by public or private right-of-way.

"Pathological waste" means human tissues, organs and body parts; and the carcasses and body parts of all animals that were known to have been exposed to pathogens that are potentially dangerous to humans during research, were used in the production of biologicals or in vivo testing of pharmaceuticals, or that died with a known or suspected disease transmissible to humans.

"Regulated Medical Waste" means blood and body fluids in individual containers in volumes greater than 20 ml, microbiological waste, and pathological waste that have not been treated pursuant to Rule .1207 of this Section.

"Sharps" means and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.

"Treatment" as defined in G.S. 130A-309.26(a) (2).

General

15A NCAC 13B .1202 General Requirements for Medical Waste

Medical waste is subject to all applicable rules in 15A NCAC 13B.

At the generating facility, sharps will be placed in a container which is rigid, leak-proof when in an upright position and puncture-resistant. Contained sharps will not be compacted prior to off-site transportation. After leaving the generating facility, the container and its contents will be handled in a manner that avoids human contact with the sharps.

Blood and body fluids in individual containers of 20 ml or less which are not stored in a secured area restricted to authorized personnel prior to off-site transportation will be packaged in accordance with the regulated medical waste packaging requirements as described in Rule .1204(a)(1) of this Section or in a container suitable for sharps. Containers of blood and body fluids which are packaged in accordance with Rule .1204(a)(1) of this Section or in a container suitable for sharps as required by this Rule will not be compacted prior to off-site transportation.

Regulated medical waste will not be compacted.

15A NCAC 13B .1203 General Requirements for Regulated Medical Waste

1. Regulated medical waste will be treated prior to disposal. Acceptable methods of treatment are as follows:
 - a. Blood and body fluids in individual containers in volumes greater than 20 ml - Incineration or sanitary sewage systems, provided the sewage treatment authority is notified;
 - b. Microbiological waste - Incineration, steam sterilization, microwave treatment, or chemical treatment;
 - c. Pathological wastes - Incineration.
2. Other methods of treatment will require approval by the Division.
3. Regulated medical waste treated in accordance with Paragraph (a) of this Rule may be managed in accordance with 15A NCAC 13B .0100 - .0700.
4. Crematoriums are not subject to the requirements of Rule .1207(3) of this Section.
5. A person who treats Regulated medical waste at the generating facility or within an integrated medical facility is not subject to the storage and record keeping requirements of Rule .1207(1) of this Section.
6. Generating facilities and integrated medical facilities in operation on October 1, 1990 that incinerate Regulated medical waste are not subject to the requirements of Rule .1207(3)(a-l) of this Section until January 1, 1995.

15A NCAC 13B .1204 Requirements for Medical Waste Generators (NA)

A person who ships regulated medical waste from the generating facility for off-site treatment shall meet the following requirements:

(1) Regulated medical waste shall be packaged in a minimum of one plastic bag placed in a rigid fiberboard box, rigid drum, or other rigid container constructed in a manner that prevents leakage of the contents. The plastic bag shall be impervious to moisture and have a strength sufficient to preclude ripping, tearing or bursting the waste-filled bag under normal conditions of usage and handling. Each bag shall be constructed of material of sufficient single thickness strength to pass the 165-gram dropped dart impact resistance test as prescribed by Standard D 1709-91 of the American Society for Testing and Materials, which is incorporated by reference including subsequent amendments and editions, and certified by the bag manufacturer. A copy is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Solid Waste Management, 401 Oberlin Road, Raleigh, North Carolina. Copies may be requested by mail at American Society for Testing and Materials, 1916 Race Street, Philadelphia, P.A. 19103 or by calling (215) 299-5400 for a cost of twelve dollars (\$12.00) plus one dollar and fifty cents (\$1.50) for shipping and handling unless prepaid, then the fee is twelve dollars (\$12.00).

(2) Regulated medical waste shall be stored in a manner that maintains the integrity of the packaging at all times.

(3) Each package of regulated medical waste shall be labeled with a water-resistant universal biohazard symbol.

(4) Each package of regulated medical waste shall be marked on the outer surface with the following information:

- (A) the generator's name, address, and telephone number;
- (B) the transporter's name, address, and telephone number;
- (C) storage facility name, address, and telephone number, when applicable;
- (D) treatment facility name, address and telephone number;
- (E) date of shipment; and
- (F) "INFECTIOUS WASTE" or "MEDICAL WASTE".

Records of regulated medical waste shall be maintained for each shipment and shall include the information listed in this Paragraph. This information shall be maintained at the generating facility for no less than three years.

- (1) amount of waste by number of packages (piece count);
- (2) date shipped off-site;
- (3) name of transporter;
- (4) name of storage or treatment facility.

The requirements of this Paragraph shall not apply to persons who generate less than 50 pounds of regulated medical waste per month.

A plan to ensure proper management of regulated medical waste shall be prepared and maintained at the generating facility.

Transportation

15A NCAC 13B .1205 Requirements for Transporters of Regulated Medical Waste

A person who transports Regulated medical waste that has not been treated at the generating facility shall meet the following requirements:

1. Transporters shall not accept waste which is improperly packaged.
2. Regulated medical waste shall be transported in a manner that prevents leakage of the contents of the package.
3. The integrity of the package shall be maintained at all times.
4. The labeling and marking of the package shall be maintained at all times.
5. All loads containing Regulated medical waste shall be covered during transportation.
6. The universal biohazard symbol shall be displayed on all transportation vehicles, in accordance with Department of Transportation Standards and 49 CFR 172 Subpart F.
7. Regulated medical waste shall be delivered to a permitted storage or treatment facility within seven calendar days of the date of shipment from the generator.
8. 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 calendar days.
9. 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.
10. 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.
11. 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.

Volumes

Estimate in tons per month expected amount of waste to be managed at the operation:

Waste Stream	Estimated 2017 Tonnage	
	Weight Per Month (lbs.)	Weight Per Month (Tons)
RMW Bio	91,650.00	45.83
RMW Chemo	2,670.00	1.34
RMW Pathology	5,720.00	2.86
RMW Pharmaceutical	1,000.00	0.50
Sharps Waste - Bio	131,000.00	65.50
Sharps Waste - Chemo	5,000.00	2.50
Sharps Waste - Pharm	13,000.00	6.50
Est. Total	250,040.00	125.02

Daniels Sharpsmart, Inc. may expect to grow past these volumes up and to 40 tons per day. Financial Assurance Mechanism will continuously be updated to reference the cost to remove five (5) days waste upon growth.

Responsibilities

The procedures established in this plan apply to all personnel handling and/or managing medical waste at the Gastonia, NC Medical Waste Processing & Treatment Facility.

The DSI *Facility Manager* will be responsible for day to day operations to include personnel have the required training and are competent in the practices for managing the waste streams. The Facility Manager is responsible for training of all workers and ensuring that medical wastes are handled, transported, packaged, stored, processed, treated and/or transferred properly and safely in accordance with all applicable local, state and federal regulations. Facility Managers will promote a safety culture for the safe handling of Medical Waste. Facility Management must also provide the equipment necessary to maintain compliance and to work safely with the facility for site workers. The Facility Manager will also oversee all operations within the facility.

Site workers (i.e. production asst., Washsmart operator, autoclave operator, drivers, etc.) are responsible for the safe handling and processing of RMW. Site workers are obligated to follow the instructions of the Facility Manger concerning medical waste handling, storage, transport, processing, treatment, and/or transfer of Medical waste.

Compliance Manager is responsible for providing guidance, and for monitoring site compliance with mandated medical waste regulations. The Compliance Manager will also maintain relationships with NC DENR Regulators to ensure compliance and communication. Compliance is available to provide training when requested.

Contact Persons/Hours of Operation

Primary Contact

Facility Manager: TBD

Regional Operations Director: Evan August, 423 – 432 – 1099, EAugust@DanielsHealth.com

Director of Compliance: Alan Larosee, 312 – 515 – 8912, ALarosee@Danielshealth.com

Compliance Manager: Kyle Little, 312 – 285 – 9087, KLittle@DanielsHealth.com

Backup Contact

VP of Operations: Daniel Kennedy, 312 – 590 – 4069, DKennedy@DanielsHealth.com

Emergency or After Hours Contact

1. In the event of any emergency or perceived emergency, call 911.
2. In the event of any emergency the Facility Manager, Regional Manager, Compliance Manager, and property manager will be notified within one (1) hour of the incident – in that order.
 - a. All incidents will be followed-up by a written report to the Compliance Manager within five (5) working days.
3. For any after-hours concerns regarding the facility, contact the 24-hour emergency number 888-952-5580 or any of the Primary or Backup contacts listed above.

North Carolina Department of Environmental Quality (NCDEQ)

Engineering Project Manager: Larry Frost, 828 – 296 – 4704

Waste Mgt. Coordinator: William (Bill) Patrakis, 919 – 707 – 8290

Solid Waste Inspector: Kim Sue, 704 – 235 – 2163

Hours of operation

Daniels SharpSmart, Inc. processing and treatment facility in Gastonia, NC is not seasonal and will operate all months of the year. General hours of operation are 24 hours per day, 7 days per week.

Site Security and Access Control

Waste is collected and transported in closed, secure and permitted trucks/trailers. The doors to the storage area of each collection truck or trailers are secured during transport or whenever a Daniels Sharpsmart, Inc. employee is not in attendance with the vehicle, including waiting to be loaded/unloaded. All trucks are labeled to alert the public regarding the type of waste being transported or handled in accordance with state and federal markings.

All property will be secured accordingly to prevent theft/and or damage. Surrounding the facility is fully fenced with barbed wire at its top in addition to a gated entrance/exit with Key Pad Access. All access roads are of all – weather construction. Daniels will also work to ensure cameras at installed and alarms are working properly. The facility interior and exterior will be monitored continuously by cameras and plant management.

All company equipment including doors, entrances, trucks and trailers will be secured by locks/bolt locks when not in use or unattended.

Signage

Exterior Warning signs, stating in English that “Caution- Biohazardous Waste Storage Area- Unauthorized Persons Keep Out” must be posted on entry doors. Signs will be readily legible during daylight from a distance of at least 25 feet.

Interior signage will be within the site to direct traffic within the facility and waste flow throughout. Signs will also provide a description of the type of waste received, the type of waste prohibited, operating hours, permit number, and emergency contact phone numbers.

Upon issuance of the permit, Daniels Sharpsmart, Inc. will post a sign near the entrance of the facility indicating; facility name, Solid Waste permit # and 24 hour emergency.

Operational Process (Overview)

Daniels Sharpsmart, Inc. revolutionary, reusable and disposal systems set new standards in health & safety including infection control, environmental effectiveness, and logistical cost savings. These types of containment systems incorporate a unique process flow from point of generation to ultimate disposal.

Regulated Medical Waste (RMW) is source segregated and disposed by licensed medical waste generators in Daniels UN certified, DOT tested reusable sharps containment systems. Once the sharps container is full, authorized personnel at the healthcare facility (generator) close and lock the contents inside. Trained staff wearing appropriate PPE place the containers on an internal cart that is transferred down to the hospital storage area. The containers are taken off the cart and placed inside a “transporter”, which closes and locks the containers inside.

“Soft” or “bulk” Regulated Medical Waste is contained in DOT tested RMW containers (non – sharps waste in corrugated reusable plastic or single – use boxes). These containers have a primary liner which accompanies every container for bulk RMW. The transporters filled with sharps containers and the bulk RMW containers are then loaded on a permitted truck for transport to the Daniels Treatment Facility.

Once delivered to the Daniels Facility by approved Medical Waste Transporter (i.e. Daniels Sharpsmart, Inc., other permitted carrier), authorized trained personnel (wearing appropriate PPE) will off-load the Transporters and bulk RMW containers from the docked trucks to stage in designated areas for segregation, transfer and/or processing. Waste transferred off – site will be treated by approved alternative technology (i.e. incineration, microwave, etc.). The waste that is segregated for processing, will be robotically decanted by Washsmart Machine (from re-usable sharps containers only) or directly loaded into specialized autoclave bins (from bulk RMW container) intended for treatment within the autoclave.

Waste from Daniels reusable sharps containers are automatically decanted into the autoclave bin then processed through the Washsmart Machine, the empty containers are sterilized by high temperature water (180 Degrees F) and non – hazardous detergent.

Waste from Daniels bulk RMW containers are decanted by bin tipper (or manual means) into the autoclave bin and processed through the autoclave. Empty reusable bulk RMW containers are sterilized by a high powered pressure washer and non – hazardous detergent.

Once the waste is loaded into the autoclave bins, the bins are manually moved into the autoclave for treatment. The door of the autoclave is secured, and the vessel is brought up to proper temperature, pressure, and for appropriate duration dictated by set operating parameters outlined in accordance with 15A NCAC 13B .1207 (2). The autoclave is a Mark Costello Model AS510

This process treats the waste as such so that it is no longer considered RMW, but is now considered municipal solid waste. As the newly classified waste is removed from autoclave vessel it is disposed of within a sealed compactor ready for final disposal in approved landfill. The standard operations of the industrial autoclave, boiler, Washsmart uses electrical, gas, and water of adequate source. Water generated is directly discharged into the local POTW. All floor drains will discharge directly to an approved sanitary sewage system. Ventilation will be provided and will discharge so as not to create nuisance odors.

Device Reclamation Program – Device Mining

Third Party Reprocessors (TPR) reprocess used medical equipment (UME) by disassembling, cleaning, sharpening, repairing, sterilizing and repackaging, then selling the UME back to hospitals at a fraction of original cost. The TPR industry is FDA regulated, saved US hospitals over \$250 million annually in 2012 and markedly reduces waste to landfill.

Daniels Sharpsmart, Inc. S32 and S64 Access Plus Sharpsmart containers are routinely used to collect and transport used medical devices from healthcare facilities for autoclaving and landfilling. This process was wasteful of UME, inconsistent with hospital sustainability, and expensive.

Under DSI UME process, DSI will harvest UME from used medical equipment containers R14 and R14 in addition to Daniels S32 and S64 Access Plus reusable Sharpsmart containers, repackage, then ship to FDA registered TPR. Used Medical Equipment for Reprocessing are not regulated as medical waste under DOT exemption 173.134 (12) (i).

OSHA requirements applicable to medical equipment provide an adequate level of safety in transportation and it is unreasonable and impractical to require RMW packaging and hazard communication for medical equipment that are intended for reuse (see 60 FR 48780; 9/20/1995).

Additionally, Daniels containers are rated DOT PG II for puncture resistance, thus further eliminating the need for secondary packaging while in transport.

§173.134 Class 6, Division 6.2—Definitions and exceptions.

(12) Laundry and medical equipment and used health care products, as follows:

(i) Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment being transported for disposal.

DSI has developed a purpose-built machine to decant the containers and enable the MD to be safely harvested prior to compliantly packaging them for transport to TPR. In addition to engineering and management controls implemented by DSI, staff will be trained to safely carry out their duties and offered relevant vaccination. This process is within full compliance of OSHA BBP Standard 1910.1030(d) (4) (iii) (A) (4).

Standard Operation Procedures

Medical Device Mining Operation and processes are outlined in *DSI SOP 17.0 Harvesting Medical Devices*. This SOP will be made available upon request.

Waste Acceptance Protocol

Daniels Sharpsmart, Inc. Treatment and Processing Facility in Gastonia, NC will accept, process, transfer or treat Regulated Medical Waste as defined in **15A NCAC 13B .1201 Definitions**. Regulated Medical Wastes accepted at this facility include Regulated Medical Waste including Pathological waste.

Pathological waste will be accepted, processed (weighed/scanned in, consolidated, and stored), transferred off – site, and then treated in accordance with the applicable States rules and regulations for approved treatment methods (i.e. incineration, Microwave, etc.). Tentatively, waste will be transferred to Med Assure in Indianapolis, IN for treatment.

All waste brought to this facility or transferred will be properly packaged and labeled in accordance with local, state, and federal requirements. Waste will be staged/stored in a non – putrescent state and/or will be refrigerated between 35 and 45 degrees if onsite longer than 7 days.

Other on – site activities/processes/treatments (not regulated under 15A NCAC 13B .1200)

Trace Chemotherapy, Non – Hazardous Pharmaceutical, and/or sharps waste in reusable sharps containers will be processed through the reusable Washsmart system. Waste will be robotically decanted into an autoclave bin for on – site treatment (steam sterilization). These waste streams may also be accepted in single – use containers, which will be processed and directly loaded into autoclave bin.

Accepted waste types

Regulated Medical Waste (RMW):

Regulated medical waste shall be packaged in a minimum of one plastic bag placed in a rigid fiberboard box, rigid drum, or other rigid container constructed in a manner that prevents leakage of the contents. The plastic bag shall be impervious to moisture and have a strength sufficient to preclude ripping, tearing or bursting the waste-filled bag under normal conditions of usage and handling. Each bag shall be constructed of material of sufficient single thickness strength to pass the 165-gram dropped dart impact resistance test as prescribed by Standard D 1709-91 of the American Society for Testing and Materials, which is incorporated by reference including subsequent amendments and editions, and certified by the bag manufacturer

Sharps:

Sharps shall be placed in a container which is appropriately labeled, rigid, leak-proof when in an upright position and puncture-resistant. Contained sharps shall not be compacted prior to off-site transportation. After leaving the generating facility, the container and its contents shall be handled in a manner that avoids human contact with the sharps. Sharps waste will be decanted in accordance with OSHA requirements.

Pathological Waste:

Packaged in a minimum of one plastic bag placed in a rigid fiberboard box, rigid drum, or other rigid container constructed in a manner that prevents leakage of the contents. The plastic bag

shall be impervious to moisture and have a strength sufficient to preclude ripping, tearing or bursting the waste-filled bag under normal conditions of usage and handling. Each bag shall be constructed of material of sufficient single thickness strength to pass the 165-gram dropped dart impact resistance test as prescribed by Standard D 1709-91 of the American Society for Testing and Materials, which is incorporated by reference including subsequent amendments and editions, and certified by the bag manufacturer.

Non Hazardous Pharmaceutical Waste:

Pharmaceutical means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321(g)(1)).

For purposes of this part, "pharmaceutical" does not include any pharmaceutical that is regulated pursuant to either of the following:

1. The federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C.A. Sec. 6901 et seq.). This waste stream shall be handled as a hazardous waste under the authority of Chapter 6.5 (commencing with Section 25100) of Division 20.
2. The Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9).

Clear labeling and an easy identifiable design (and color) for Daniels Reusable Non – Hazardous Pharmaceutical containers encourage and ease proper waste segregation by the generator. Reusable Non – Hazardous Pharmaceutical Containers are designed and labeled to handle Non – Hazardous Pharmaceutical Waste only.

Non-RCRA hazardous pharmaceutical wastes are placed into an appropriately labeled pharmaceutical (sharps) container (reusable or single use) at the respective healthcare generator.

Pharmaceutical waste will be brought into the facility in rigid, puncture-resistant containers that are appropriately labeled and transported to the DSI treatment facility in a manner that retains the integrity of the container.

Trace Chemotherapy Waste:

Trace chemotherapeutic waste means waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, including, but not limited to, gloves, disposable gowns, towels, and intravenous solution bags and attached tubing that are empty. A biohazardous waste that meets the conditions of this paragraph is not subject to the hazardous waste requirements

Trace chemotherapy is defined below as vials or other containers that have less than 3% of the original contents by weight, after removing as much of the chemotherapy feasible. It also includes the chemotherapy remaining in all needles, bags, tubing, containers, gloves, and gowns used during chemotherapy infusions. When less than 3% of the original content remains in total, the items may be considered RCRA empty.

Clear labeling and an easy identifiable design (and color) for Daniels Reusable Trace Chemotherapy containers encourage and ease proper waste segregation by the generator.

Reusable Trace Chemotherapy Containers are designed and labeled to handle Trace Chemotherapy waste only.

Brought into the facility in rigid, puncture resistant containers that are appropriately labeled and transported to the DSI treatment facility in a manner that retains the integrity of the container.

Storage

15A NCAC 13B .1206 Requirements of Storage of Regulated Medical Waste

A person who stores Regulated medical waste that has not been treated at the generating facility will meet the following requirements:

1. Regulated medical waste will be stored in a manner that prevents leakage of the contents of the package.
2. Regulated medical waste will be stored in a manner that maintains the integrity of the packaging at all times.
3. The labeling and marking of the package required in Rule .1204 of this Section will be maintained at all times.
4. Prior to treatment, all Regulated medical waste will be confined to the storage area.
5. Regulated medical waste will be stored prior to treatment for no more than seven calendar days after receipt.
6. Regulated medical waste will not be stored longer than seven calendar days from the date of shipment from the generator unless the Regulated Medical Waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit. Daniels SharpSmart will have a refrigerated trailer on site in the event refrigeration is needed.
7. Regulated medical waste will be stored no longer than seven calendar days after treatment.
8. Only authorized personnel will have access to areas used to store Regulated medical waste.
9. All areas used to store Regulated medical waste will be kept clean. Vermin and insects will be controlled.
10. All floor drains will discharge directly to an approved sanitary sewage system. Ventilation will be provided and will discharge so as not to create nuisance odors.
11. This plan will be prepared, maintained and updated as necessary to ensure continued proper management of Regulated medical waste at the facility.
12. Only authorized personnel will have access to areas used to store Regulated medical waste.
13. All areas used to store Regulated medical waste will be kept clean. Neither carpets nor floor coverings with seams will be used in storage areas. Vermin and insects will be controlled.

Unauthorized Waste

Wastes such as any hazardous waste (RCRA) and any waste regulated by the Nuclear Regulatory Commission cannot and will not be accepted for transport or processing at this facility. Such wastes will be managed in accordance with the Unauthorized Waste Plan. Daniels Sharpsmart, Inc. reserves the right to reject waste for pick-up or treatment if the package is:

- Leaking
- Incorrectly packaged
- Mislabeled or unlabeled
- Damaged
- No applicable permits
- Out of compliance with regulatory or agreement procedures

Wastes not accepted for treatment include:

- Radioactive wastes;
- Hazardous (RCRA) wastes as defined by the Environmental Protection Agency (EPA);
- Chemicals, Explosives, Radioactive, Mercury, and other hazardous waste.

Unauthorized Waste Plan

Unauthorized waste. In the event of receiving waste that is unauthorized for transfer, treatment, or incorrectly labeled on the manifest the following will be followed:

1. The facility will keep an incident log if any unauthorized waste (hazardous, etc.) or improperly labeled waste (i.e.; RMW and incinerable waste in the same container) or improperly packaged waste (bags not tied off) is encountered.
2. The log will state the date of waste reception, generator information, and actions taken by the facility.
3. Random inspection of containers will be conducted and documented when the items are off loaded from route trucks for storage. Employees are not authorized to manually open any box or bagged waste. This will be conducted at the facility manager's discretion by mechanical means.
4. Major or repeated violators Action Protocol
 - a. Major or repeated violations are defined as more than 2 unauthorized waste incidents from one generator in a month.
 - b. The facility manager will contact the generator's Field Service Manager or the Area Operations Manager in order for them to contact the generator.
 - c. The generator will be informed of the incident and requested to submit a written follow up report on waste segregation.
 - d. The NCDENR and Daniels Compliance will be notified of major or repeated violators within 7 business days of the incident. The notification will include the generator information, actions taken by the facility, and any written response from the generator.

Unauthorized Waste Log

Date of Unauthorized Waste Received	Generator (if known)	Action Taken by Facility	Generator Contacted (Date and whom)	Generator Action Taken	DNR Contacted (Date and whom)



Disposal Facility

Regulated Medical Waste that is treated on – site through steam sterilization technology will be removed from autoclave vessel and disposed within an on – site sealed compactor ready for final disposal in approved landfill. Currently, Daniels does not have any contracts/agreements with specific disposal facilities to accept municipal solid waste out of our Gastonia, NC processing & treatment facility. Once the operational process is confirmed, we will note the disposal facility details within this operations manual.

Daniels Sharpsmart, Inc. will ensure wastes taken to the disposal facilities are in accordance with the disposal facilities service area and any applicable local, state, and federal regulations. Daniels compliance team will acquire the proper permits, licenses, and documents to ensure this compliance. Additionally, Daniels will maintain a signed copy of the Certificate of Destruction on file for a minimum of 3 years that will be made available upon request.

Equipment

Please see attached autoclave specifications

Steam sterilization requirements:

- (a) Steam under pressure will be provided to maintain a minimum temperature of 250 degrees Fahrenheit for 45 minutes at 15 pounds per square inch of gauge pressure during each cycle; or other combinations of parameters that are shown to effectively treat the waste.
- (b) The steam sterilization unit will be provided with a chart recorder which accurately records time and temperature of each cycle.
- (c) The steam sterilization unit will be provided with a gauge which indicates the pressure of each cycle.
- (d) Monitoring under conditions of full loading for effectiveness of treatment will be performed no less than once per week through the use of biological indicators or other methods approved by the Division.
- (e) Regulated medical waste may be disposed of until or unless monitoring as required in Sub-Item (2) (d) of this Rule does not confirm effectiveness.
- (f) A log of each test of effectiveness of treatment performed will be maintained and will include the type of indicator used, date, time, and result of test.

Boiler

Please see attached Parker Boiler Specifications

Boiler BTU input (not output): 860 (1,000 BTU/HR)

Fuel used (probably natural gas): Natural Gas

Any backup fuel: No

Estimated volatile organic compound emissions: Below 5PPM

Washsmart

Please see attached Washsmart 6000 Specifications

Autoclave

Please see attached Mark Costello Autoclave Specifications

Mfr Part No.: AS510

Manufacturer: MARK COSTELLO COMPANY

Contract No.: GS-07F-5447P (ends: Nov 23, 2013)

MAS Schedule/SIN: 073/384 9

Weight: 1.000 LB

Process temperature: 250F

Estimated Volume – Two (2) bins per load @ 375 lbs. per bin.

Actual and maximum number of loads per day: Actual 8, Maximum 24

Process control and records will be maintain on the autoclave circular chart to record time, temperature, and pressure. All records will be maintained at the facility for a minimum of three (3) years. Operation and efficacy testing will be in accordance with NCDENR rules and regulations

Cleaning and Decontamination

Plan for maintaining facility property in a sanitary condition and actions to be taken to minimize noise, vectors, and odors. All waste should be segregated, stored, and contained properly throughout the day and checked at the beginning and ending of each shift.

1. Daily cleaning at the end of every shift and/or as needed will be accomplished to minimize odor, potential litter, insects and/or rodents at this facility.
2. Disinfection will be accomplished through the use of a hypochlorite cleaning solution.
3. Frequency of cleaning will depend on usage and the operational environment. There are four distinct operations to be conducted at the facility. This also includes all areas where waste has traveled.
 - a. Inbound and outbound staging areas including storage areas.
 - i. Cleaning and disinfection on a daily basis.
 - ii. Containers will be checked to ensure integrity of packaging
 - iii. Leaks, spills, material will be cleaned to ensure floor and housekeeping
 - iv. All drains/vents will be check for potential buildup
 - v. Scales and weigh stations will be cleaned
 - b. Waste containers will be decanted into autoclave bin (by manual or automatic means) before treatment
 - i. Cleaning of such operations will be conducted on a daily basis.
 - ii. Disinfection of spill, leaks or otherwise potential health hazards will be conducted on an as need basis.
 - c. Washing of the re-usable sharps containers in the Washsmart System and power washing station. Parts of the Washsmart System in direct contact with Medical Waste and effluent should be cleaned every shift (i.e. Washsmart pit and conveyor)
 - i. Caution will be used due to the waste containing contaminated sharp items.
 - ii. Cleaning of such operations will be conducted on a daily basis.
 - iii. Disinfection of spill, leaks or otherwise potential health hazards will be conducted on an as need basis.
 - d. Treating Regulated Medical Waste via Steam Sterilization
 - i. Cleaning of such operations will be conducted on a daily basis.
 - ii. Disinfection of spill, leaks or otherwise potential health hazards will be conducted on an as need basis.
 - iii. Attention will be in and around the autoclave including the pit for any residual or accumulated water.
4. Provision of cleaning equipment and suitable convenient cleaning facilities will be made to ensure that the cleaning tasks are carried out safely and effectively. A list of the basics follows:
 - a. Hot water trigger action hose long enough to reach inside washer and 90 degree conveyor.
 - b. Stiff (wire) brushes for cleaning washer filters.
 - c. Long handled tongs for picking up sharps.
 - d. Long handled brush for sweeping floor.
 - e. Dust pan and brush.
 - f. Reusable hand spray bottle to fill with detergent and water.
 - g. Heavy duty waterproof gloves.
 - h. Goggles.
 - i. Decontamination of Reusable Secondary Containers

- j. Reusable secondary containers (garbage cans, bins, etc.) should be decontaminated each time they are emptied unless they are protected from contamination by disposable liners, bags, or other devices removed with the waste. These containers should be maintained in a clean and sanitary manner.
- k. Approved methods of decontamination include, but are not limited to, agitation to remove visible soil combined with one of the following procedures:
 - i. Exposure to hot water of at least 82 °C (180 °F) for a minimum of 15 seconds.

Emergency Actions

Contingency plans for equipment breakdown, spills, noise, odors, unusual traffic patterns, and/or long-term power outages affecting the equipment.

In the event of any emergency or perceived emergency, call **911**. For any after-hours concerns, contact the 24-hour emergency number 888-952-5580 or any of the Primary or Backup contacts listed on page 15.

Personnel Exposures or Contamination

1. Remove the exposed or contaminated personnel from the contaminated area, unless it is unsafe to do so due to the medical condition of the victim or potential hazard to the rescuer
2. If the incident occurs during normal working hours, notify COMPLIANCE or the site operations manager.
3. Administer first aid as appropriate
4. Remove any contaminated clothing
5. Proceed to the nearest emergency eyewash/shower to flush contamination from the eyes and skin
6. Stand by to provide emergency information.
7. Call Medcor for additional instructions (company triage)

Contamination of Facilities

- DO NOT attempt any cleanup or decontamination procedures alone or without wearing Personal Protective Equipment (PPE), including respiratory protection if respiratory pathogens may be present. Unless the spill is minor and well defined do not clean up the material without Compliance or facility management approval.
- Avoid spreading contamination by limiting access to the contaminated equipment or area only to individuals who are properly protected and trained to respond to all types of hazards that exist
- If the spill involves a liquid, place absorbent material on the spill and decontaminate with an approved disinfectant for a minimum of a 10-minute contact time.
- If sharps are involved, pickup using a mechanical means, such as tongs, forceps, or dustpan and broom. DO NOT USE YOUR HANDS to pick up any sharp items, even if gloves are worn.
- Decontaminate area under a supervisor's direction using appropriate methods.
- Stand by to provide emergency information and assistance to Emergency Response Personnel, if required.

Release to the Environment (air, water, soil)

- Stop the release, if safe to do so.
- Follow procedures described above for contamination of facility.
- Make immediate notifications. Any information of a release or discharge of Regulated Medical Waste from or of a fire or explosion at a Special Medical Waste facility which could threaten the environment or human health outside the facility. The description of the occurrence and its cause will include:
 - a. Name, address, and telephone number of the owner or operator;
 - b. Name, address, and telephone number of the facility;
 - c. Date, time, and type of incident;
 - d. Name and quantity of material(s) involved;
 - e. The extent of injuries, if any;
 - f. An assessment of actual or potential hazards to the environment and human health outside the facility, where this is applicable; and
 - g. Estimated quantity and disposition of recovered material that resulted from the incident.

Transferred Waste Due to Emergency

1. In the unlikely event that Regulated Medical Waste must be transported off site, all Regulated Medical Waste and sharps will be moved in compliant containers for processing.
2. Waste would be taken to the following back-up location:
 - a. Daniels Sharpsmart, Inc. Baltimore, MD
 - b. Daniels Sharpsmart, Inc. Gadsden, AL
 - c. Curtis Bay Energy Baltimore, MD (Incinerator)
3. DSI will not store biohazardous or sharps waste at the facility for not more than 7 days before refrigeration unless approved by the department.
4. Refrigerated trucks will be leased as a contingency should weather or other unforeseen condition result in need to store material on-site in excess of 7 days.

Natural Disasters

The on-site employee will immediately notify, via his/her cell phone, the local emergency services or 911, if necessary. The employee will immediately notify Daniels Sharpsmart, Inc. corporate office or operations manager of any emergency occurrence.

Personnel Accountability during emergencies

Employee safety is priority: The Emergency Response Coordinator will determine if implementation of evacuation is appropriate. Employees will be notified of evacuation by loud speaker or yelling. Each Daniels Facility will have a designated safety committee for safety/emergency events.

Personnel accountability is the initial responsibility of the employee in charge:

- a. Identify all personnel;
- b. Locate all personnel and get them to the rally point at the end of the employee parking lot towards Chespark Dr.
- c. Know the name and last known location of anyone who does not rally.
- d. Daniels Sharpsmart, Inc. personnel will not engage in rescue operations. This will be left to Emergency Management Services.

Spills

In the event of a spill, the following procedure will be followed. Daniels Treatment Facility will have Spill Kits available in all processing areas.

Spill Procedures

Employees can minimize small spills by carefully inspecting all containers and following safe handling procedures. If a spill occurs, it will be small and can be handled by employees immediately.

Following a spill of regulated medical waste or its discovery, the following procedures will be implemented:

1. Identify the nearest Spill Kit.
2. Take appropriate precautions to ensure personnel do not come into contact with any contaminants by wearing appropriate personal protective equipment.
3. Contain spilled waste in accordance with the packaging requirements of DOT, OSHA, and NCDENR.
4. Clean and disinfect any areas having been contacted by regulated medical wastes. Materials used to decontaminate the area will be disinfectants effective against mycobacteria.
5. Take necessary steps to replenish containment and cleanup kit.

If a larger spill results, for example, from a vehicular accident during transit, where waste is scattered over a large area; the employee must contact the Daniels Facility Manager or Compliance Manager immediately for instructions and assistance. Daniels will **notify NC state DOT and NCDENR** and contact the contracted major spill service, if necessary, to perform any necessary biohazard abatement. The employee will don personal protective equipment and secure the area to the best of his/her ability. He/she will clear the area of all non-essential personnel and contain the spill as much as possible. He/she should also inform the authority present of the nature of the material involved. When company

personnel arrive, the spill cleanup procedures will be followed.

Spill Containment and Clean up Kit

All regulated medical waste management facilities are required to keep a spill containment and cleanup kit within the vicinity of any area where regulated medical wastes are processed, and the location of the kit will provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting regulated medical wastes are required to carry a spill containment and clean up kit in the vehicle whenever regulated medical wastes are conveyed. The kit will consist of at least the following items:

1. Material designed to absorb spilled liquids. The amount of absorbent material will be that having a capacity, as rated by the manufacturer, of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or 10 gallons, whichever is less.
2. One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream at a distance. The disinfectant will be hospital grade and effective against mycobacteria.
3. Enough red plastic bags to enclose 150% of the maximum load accumulated or transported (up to a maximum of 500 bags), that meet the applicable requirements of 49 CFR Part 173 or an exemption approved by the United States Department of Transportation. These bags will be large enough to over pack any box or other container normally used for regulated medical waste management by that facility.
4. Appropriate personal protective equipment.
5. For vehicles only, a first aid kit, fire extinguisher, boundary marking tape, lights and other appropriate safety equipment.

Cleanup

1. Do not leave the area unattended.
2. Do not allow unauthorized personnel into the area.
3. Access spill response kit immediately.
4. Priority will be given to prevent spill from reaching a floor drain.
5. Use broom and dustpan to pick up any spilled sharps and place them in a sharps container. If spill is a solid, collect and dispose of it in a medical waste container.
6. Apply absorbent material to isolate spilled materials to the smallest possible extent.
7. Areas contaminated with spills will then be disinfected with the approved disinfectant. Remaining disinfecting solution will be collected with absorbent material and placed in a plastic bag for decontamination treatment.
8. Clean hands with antibacterial wipes, hand sanitizer, or wash thoroughly with soap and water.

Repackaging

1. Collect spilled material and place in appropriate plastic bags and lined containers. Also collect absorbent material and place into proper packaging containers.
2. Spills resulting from leaking containers will be remediated by placing the leaking container into double plastic bags (both sealed).
3. If protective clothing becomes soiled with the spilled material, the clothing will be removed and placed in a plastic bag for decontamination treatment.
4. All spill materials collected will be treated by the steam decontamination process (off-site)
5. All spills must be immediately reported to the facility manager.

Personal Protective Equipment and Procedures

All Daniels Facility employees are trained on proper PPE (usage, donning, doffing, etc.) before they step foot on any plant floor. Appropriate personal protection equipment will be worn at all times while in the facility (on plant floor) or anytime there is potential for exposure. The following

- **Uniforms** - Uniforms or other protective clothing including coveralls and aprons will be supplied and laundered by an outside contracted service. Daniels employees are to never take their uniforms or other PPE home.
- **Work Gloves** - Hand protection (disposable latex or leather gloves) will be provided to employees and will be worn when handling infectious waste containers.
- **Personal Hygiene** – PPE used for handling waste materials must be kept in the work area or an employee's personal storage area when not in use.
- **Safety boots** – All employees working in a safety sensitive function are provided safety boots free of charge. It is required they to be worn at all times on the plant floor.
- **Safety Glasses** – Safety glasses or goggles must be worn at all times while in the plant or potential for exposure

All employees are to wash their hands or use hand sanitizer as frequently as possible. Hands must be washed before eating, drinking, smoking or using the restroom.

Employees are not allowed to eat/drink in the work area (shop floor/dock). Smoking, eating, or drinking is prohibited while the employee is handling waste containers or servicing a customer.

Employee Training

Trained employees must be onsite at all times the site is open, overseeing the management and process flow of waste.

All Daniels Sharpsmart, Inc. employees receive the following training initially and on an annual basis (if applicable):

- Bloodborne Pathogens/Diseases (Exposure Control Plan)
- Hepatitis B and tetanus (TDAP) Vaccination
- Hazard Communication
- HIPAA/HITECH and Omnibus
- PPE
- Forklift Training, if applicable
- Autoclave training, if applicable
- Washsmart training, if applicable
- DOT Training, if applicable
- Internal Policies and Procedures as applicable (i.e. harassment and sensitivity, injury reporting, etc.)

All training is documented and records will be maintained on-site and at Daniels Sharpsmart, Inc. in Chicago, IL indefinitely.

Safety Procedures

Personnel will also receive the appropriate immunizations including tetanus and hepatitis B vaccinations as accepted/required in addition to initial and annual required training.

All facility personnel are required to:

- Wear personal protective equipment (supplied daily at no cost to the employee) when handling medical waste and includes a company uniform, gloves, safety glasses and safety boots.
- Employees will be given training in first aid and spill/emergency response procedures.
- Wash their hands after de-gowning from handling waste containers.
- Gloves used when handling waste containers are not allowed in the eating and office areas.

Injuries and Exposures

If injured or exposed to infectious waste materials, the employee must report the incident immediately to a supervisor/manager. Medical treatment will be provided at a designated health care facility of applicable.

Exposure situations will require evaluation, testing and proper preventative treatment. All exposure situations will be reported to the facility manager and MedCor (Daniels triage service) – **(800) 775 5866**

Company policy requires all injuries and exposures to be reported immediately. Failure to comply will result in disciplinary action.

Record Retention/Manifesting

Daily tonnages of waste received by County of origin will be tracked and recorded by Daniels manifest/tracking document procedure. Daniels captures generator information on all waste manifests/tracking documents by a barcoding system. Also, tonnages of waste sent to a disposal facility is also tracked and recorded.

Tracking documents for Regulated medical waste will be maintained for each shipment and will include the information listed in this Paragraph.

This information will be maintained at the treatment facility for no less than three years.

- a. Name and address of generator;
- b. Date received;
- c. Amount of waste received by number of packages (piece count) from each generator;
- d. Date treated;
- e. Name and address of ultimate disposal facility.

Reporting

Regulated medical waste treatment facilities that treat waste generated off-site will submit to the Division an annual report, by August 1 of each year on a form prescribed and approved by the Division.

The form can be found at the below link:

http://portal.ncdenr.org/c/document_library/get_file?uuid=29a57661-98f1-4894-a293-70c966cb0c59&groupId=38361

Container Identification Sheet – Including, but not limited to the following: (i.e. R14 & R64 not pictured)

S14



S14PH



S22



S22PH



S32



S32PH



S14A+ (No Tray)



S22PHA+ (No Tray)



S22A+ (No Tray)



S32PHA+ (No Tray)



S32A+ (No Tray)



S64A+ (No Tray)



S64PHA+ (No Tray)



M64 (Red Top No Tray)



C22



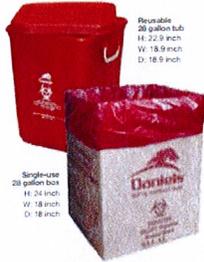
C64 (No Tray)



Bulk RMW Containers:

28 GAL

Reusable



Reusable
28 gallon tub
H: 22.9 inch
W: 18.9 inch
D: 18.9 inch

Single Use

Single-use
28 gallon bag
H: 24 inch
W: 18 inch
D: 18 inch

38 GAL



43 GAL



96 GAL



200 GAL

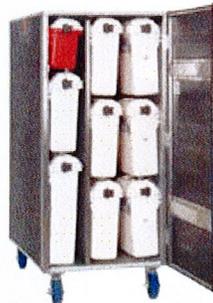


Transporters:

Small



Medium



Large



Section IV

Facility Drawing/Layout – Please see *Appendix B*

Section V

Financial Assurance

Financial Assurance - Daniels Sharpsmart, Inc. Gastonia, NC Cost Estimate

OWNER: Daniels Sharpsmart, Inc.
1851 Chespark Dr. Gastonia, NC 28052

PERMIT NO. N/A

*Estimated Monthly Volume 2017: Est. 250,000.00 lbs.

*Estimated Incoming Volume (5 days) 2017: 250,000.00 lbs. /20 workdays in a month X 5 workdays in a week = 62,500 lbs.

ITEM	QUANTITY	UNITS	UNIT COST	COST
Cost to remove and haul 5 days waste	62,500 Pounds		Table 1	\$ 5,005.00
Treatment costs (Off-site treatment facility Baltimore,MD)	62,500 Pounds		0.15	\$ 9,375.00
Landfill costs (Disposal)	62,500 Pounds		0.03	\$ 1,875.00
Landfill Transportation Cost \$650 (Compactor)	62,500 Pounds		0.02	\$ 1,250.00
Costs to clean and disinfect building (Cleanup)	28,584 Sq. Ft		\$0.25	\$ 7,146.00
Misc. Costs (Contingency Container Inventory)	2500 Containers	5 Truckloads	1350	\$ 6,750.00
Total Current Closure Costs				\$31,401.00

Table 1	
Broker, removal/loading, and Transport Fee below	
Assumptions 62,500 lbs. of waste (1 day transit from NC to AL)	
Daniels Sharpsmart, Inc. Gastonia, NC Treatment Facility to	
Daniels Sharpsmart, Inc. Gadsden AL Treatment Facility 2318 E.	
Broad Street Gadsden, AL 35903 Permit # TRTS 112811 - 2801	
62,500 per 5 day week	
Transport 12,000 lbs. per trip - about 5 trips	
Per trip cost + fuel = \$751 x 5 trips = \$3,755	\$ 3,755.00
Tractor and trailer Rental per week	\$ 1,250.00
Total	\$ 5,005.00



Waste Management
ENVIRONMENTAL QUALITY

PAT MCCRORY

DONALD R. VAN DER VAART

MICHAEL SCOTT

August 8, 2016

Emailed: KLittle@danielshealth.com

Mr. Kyle Little, Compliance Manager
Daniels Health, USA
111 W. Jackson Blvd., Suite 720
Chicago, IL 60604

**RE: Financial Assurance Closure Estimate Approval for 2016
Daniels Sharpsmart, Inc., proposed permit no. 3617-MWP-2016, medical waste facility
GASTON County, DIN No. 26576**

Dear Mr. Little,

The Division of Waste Management – Solid Waste Section (Section) has approved Daniels Sharpsmart, Inc.’s financial assurance closure estimate (2016 dollars) of \$31,401.00 which will allow 62,500 lbs. or 31.25 tons of medical waste materials per a five-day week. Daniels Sharpsmart, Inc. shall establish financial assurance mechanism(s) in the amount of \$31,401.00 prior to issuance of a permit to operate.

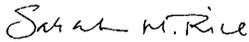
Approved closure estimate	Allowable medical waste within a 5-day week
\$31,401.00	62,500 lbs or 31.25 tons

At this time, Daniels Sharpsmart, Inc. may choose to establish financial assurance as a performance or payment bond. Once the bond is in place, a standby trust shall be established with a financial institution. The proposed permit number 3617-MWP-2016 will be needed to complete the bond and standby trust templates, which can be found at <http://go.ncdenr.gov/fa> under the header labeled, “**Mechanisms for all other Solid Waste Management Facilities:**” At no time can Daniel Sharpsmart, Inc. operate as a medical waste processing facility prior to receipt of a Permit to Operate from the N.C. Department of Environmental Quality – Division of Waste Management, Solid Waste Section.

On an annual basis, the closure amount shall be updated for inflation and a revised mechanism will be due to the Section by the establish date of the bond. Schedule A from the Standby Trust Agreement shall be updated with the revised bond amount and submitted to the Section. Should Daniels Sharpsmart, Inc. want to modify their permit in the future by increasing their tonnage and in doing so, their financial assurance, please contact Larry Frost at 828-296-4704.

Please frequently check the Section's financial assurance website <http://go.ncdenr.gov/fa> for any updates or new information that may be posted throughout the year. In the meantime, should Daniels Sharpsmart, Inc. have any questions or concerns please feel free to contact me at 919-707-8287 or sarah.rice@ncdenr.gov.

Sincerely,



Digitally signed by Sarah Rice
DN: cn=Sarah Rice, o=Division
of Waste Management,
ou=Solid Waste Section,
email=sarah.rice@ncdenr.gov,
c=US
Date: 2016.08.08 14:36:27 -04'00'
Adobe Acrobat version:
2015.007.00000

Sarah M. Rice, Compliance Officer
Division of Waste Management, Solid Waste Section

ec: Larry Frost, SWS
Jason Watkins, SWS
Ellen Lorscheider, SWS,
Ed Mussler, SWS;
Bill Patrakis, SWS
Kim Sue, SWS

Section VI

Signature Pages

Applicant signature page (see attached).

Contract operator signature page (see attached).

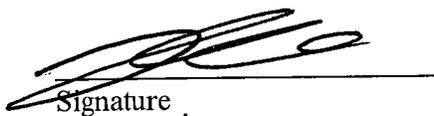
If the landowner of the property is not the applicant, the attached certification form by the land owner is required (see attached).

Signature page of applicant --

Name of facility Daniels SharpSmart, INC.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and that the information provided in this application is true, accurate, and complete to the best of my knowledge.

I understand that North Carolina General Statute 130A-22 provides for administrative penalties of up to fifteen thousand dollars (\$15,000.00) per day per each violation of the Solid Waste Management Rules. I further understand that the Solid Waste Management Rules may be revised or amended in the future and that the facility siting and operations of this solid waste management facility will be required to comply with all such revisions or amendments.



Signature

Kyle Little

Print Name

8/18/16

Date

Compliance Manager

Title

Business or organization name Daniels SharpSmart, INC.

Certification by Land Owner (if different from Applicant): Same

I hereby certify that I have read and understand the application submitted by _____ for a permit to operate a solid waste management facility on land owned by the undersigned located at (address) _____; (city) _____, NC, in _____ County, and described in Deed Book and Page(s) _____.

I specifically grant permission for the proposed solid waste management facility planned for operation within the confines of the land, as indicated in the permit application. I understand that any permit will be issued in the names of both the operator and the owner of the facility/property. I acknowledge that ownership of land on which a solid waste management facility is located may subject me to cleanup of said property in the event that the operator defaults as well as to liability under the federal Comprehensive Environmental Responsibility, Compensation and Liability Act ("CERCLA"). Without accepting any fault or liability, I recognize that ownership of land on which a solid waste management facility is located may subject me to claims from persons who may be harmed in their persons or property caused by the solid waste management facility.

I am informed that North Carolina General Statute 130A-22 provides for administrative penalties of up to fifteen thousand dollars (\$15,000) per day per each violation of the Solid Waste Management Rules. I understand that the Solid Waste Management Rules may be revised or amended in the future, and that the siting and operation of the facility will be required to comply with any such revisions or amendments.

Signature

Date

Print name

NORTH CAROLINA

_____ County

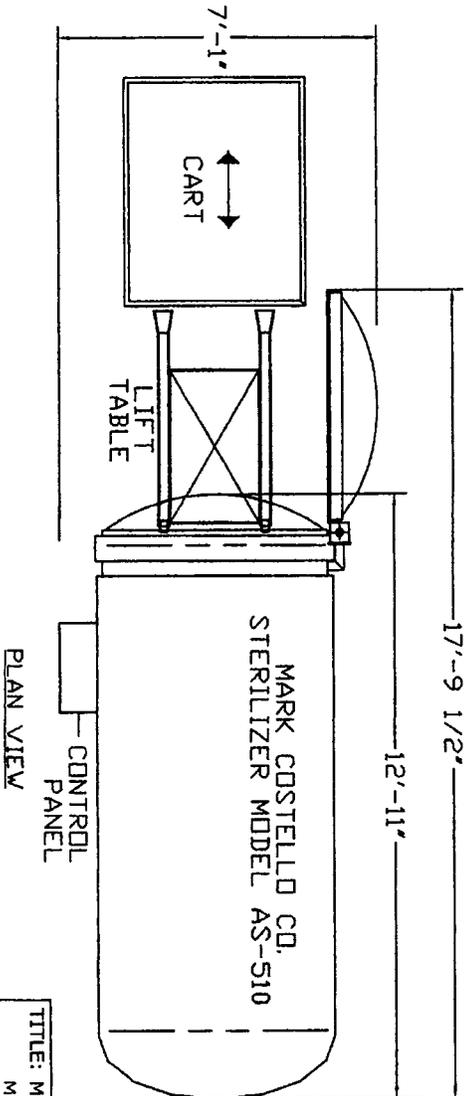
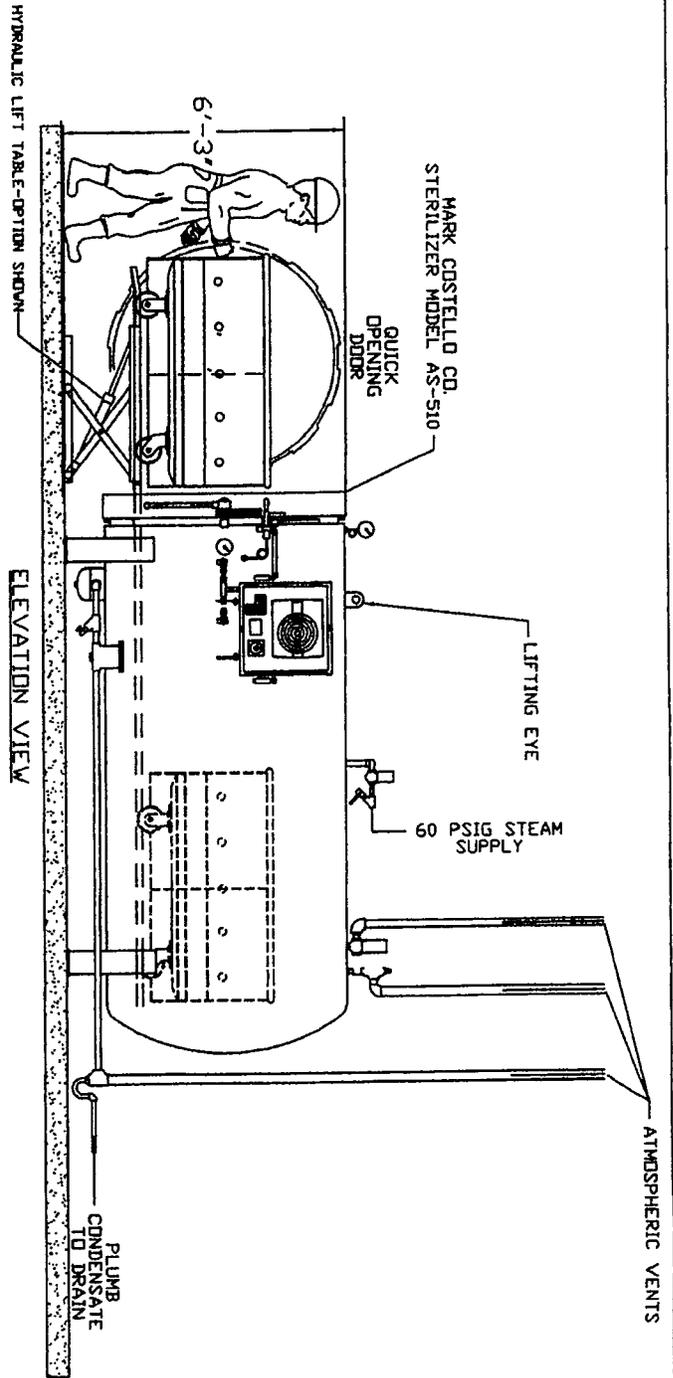
I, _____, Notary Public for said County and State, do hereby certify that _____ personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the _____ day of _____, 20__.

(Official Seal) _____
Notary Public

My commission expires _____.

Autoclave Specs



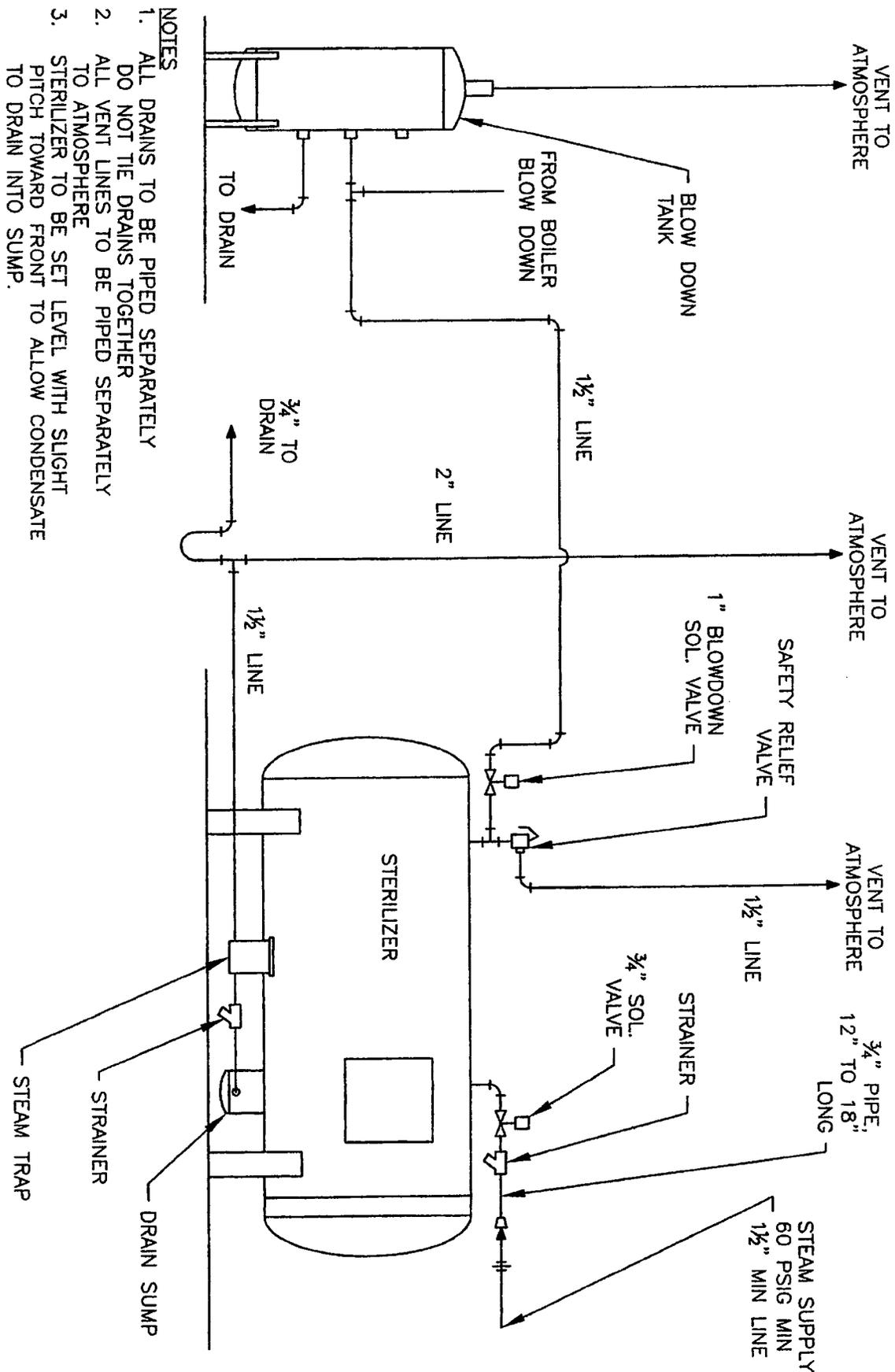
- GENERAL NOTES:**
1. ALL DIMENSIONS ARE APPROXIMATE.
 2. LEFT HAND HINGE IS SHOWN. RIGHT HAND HINGE AVAILABLE.
 3. DESIGN & CONSTRUCTION PER ASME SECTION VIII, DIV 1 FOR 75 PSIG MAXIMUM ALLOWABLE WORKING PRESSURE AT 320°F.
 4. ALL VENT LINES TO BE SEPARATELY PIPED.
 5. STRAINER & VALVES SHOWN ARE INCLUDED WITH UNIT. VENT & SUPPLY LINES BY CUSTOMER.
 6. PROVIDE 60 PSIG REGULATED STEAM SUPPLY WITH 3/4" REDUCER IMMEDIATELY UPSTREAM OF STEAM SOLENOID VALVE. SUPPLY LINE SHALL BE WELL TRAPPED & SIZED PER THE LESSER OF 1000 LBS/HK OR MAXIMUM BOILER CAPACITY WITH MAXIMUM 10 PSI PRESSURE DROP. MINIMUM RECOMMENDED LINE SIZE IS 1 1/4".
 7. INSTALLATION & SIZING OF SAFETY RELIEF VALVE (SRV) DISCHARGE & ANTI-SWING BALL APPENDIX. SEE WITH ASME SECTION VIII DIV 1 TO REDUCE BACK PRESSURE ON

TITLE: MC MEDICAL WASTE STEAM STERILIZER
MODEL AS-510 WITH HIGH VOLUME CARTS



MARK-COSTELLO CO.

DR. MK	CAD.
CK.	APP.
DATE: 01-03-05	
SCALE: AS SHOWN	
TOL: + .1/16	
DRAWING NO	75-003
WWW.MARK-COSTELLO.COM	



- NOTES**
1. ALL DRAINS TO BE PIPED SEPARATELY
DO NOT TIE DRAINS TOGETHER
 2. ALL VENT LINES TO BE PIPED SEPARATELY
TO ATMOSPHERE
 3. STERILIZER TO BE SET LEVEL WITH SLIGHT
PITCH TOWARD FRONT TO ALLOW CONDENSATE
TO DRAIN INTO SUMP.

STERILIZER AND BLOW DOWN TANK PIPING SCHEMATIC

Year built: 2003 Model: AD 510KHC
Serial #: LAAT-02410

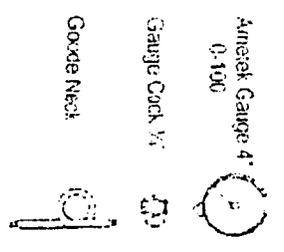


Figure A
Gauge Assembly

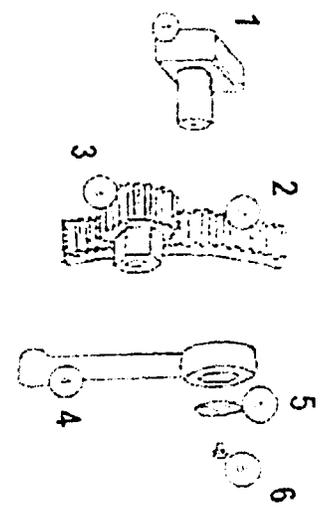


Figure B
Ratchet Rack & Pinion
Door Opener

1. Pinion Shaft
2. Gear Rack
3. Pinion Gear
4. O-R Ratchet Assembly
5. Fender Washer 3/8"
6. HHC 3/8" X 16 X 1 1/2" lg.

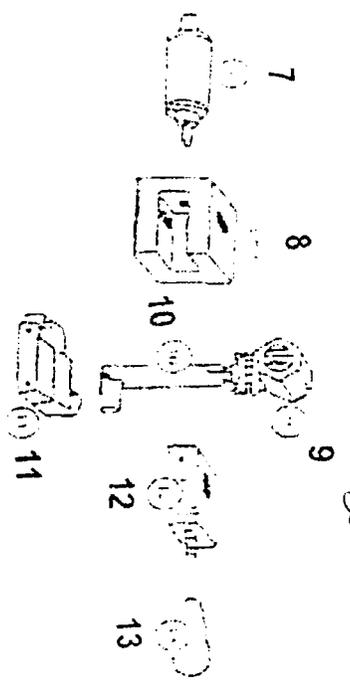
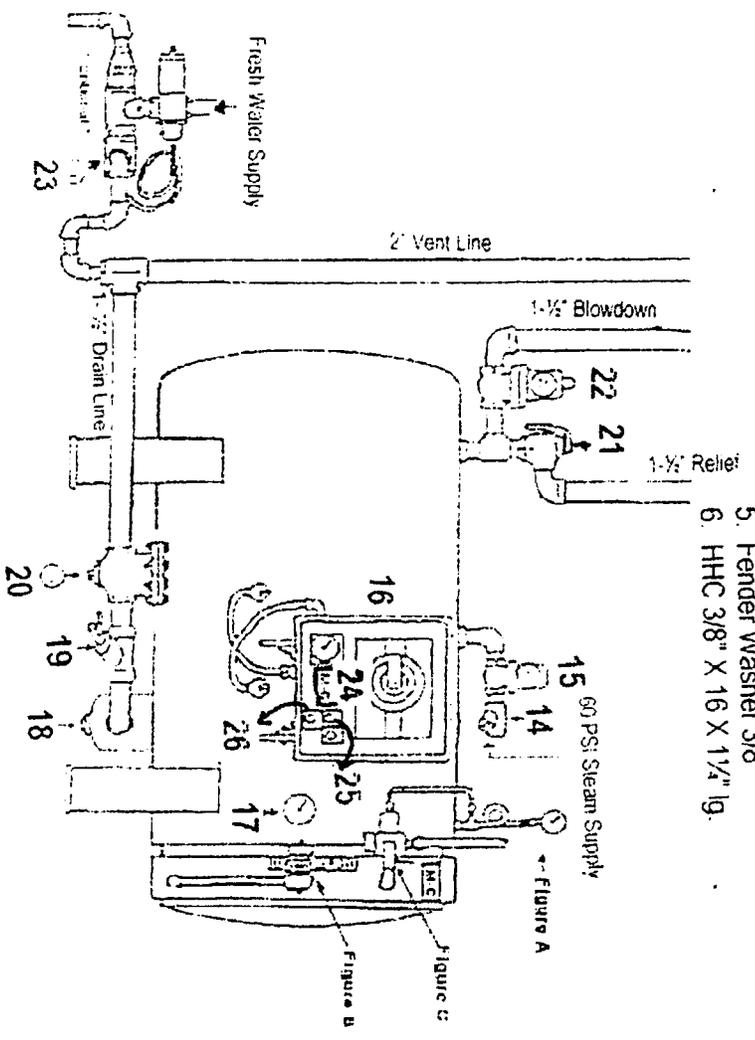


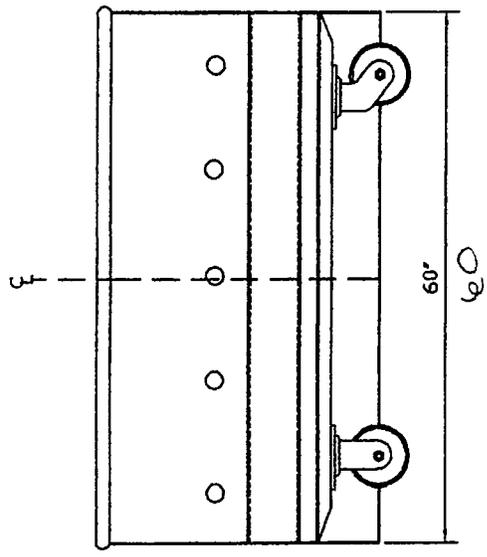
Figure C
Door Safety Assembly

7. Humphrey Air Cylinder # 5S1F with Viton
8. Safety Assembly Mounting Block
9. Jamesbury Ball Valve, 1/2" #A2236TT
10. Actuator Shaft
11. Selecta Switch (limit switch) #SS83-BZG1-2RN
12. Actuator Block
13. Jergens Aluminum Handle #10403
14. Armstrong "Y" Strainer, 3/4"
15. Magnatrol Inlet Valve #114S43
16. Control Panel (Dual Pen)
17. Bimetal Thermometer # B83204
18. Sump Drain, 9" - fit cut Basket Screen & 1 1/2" port
19. Armstrong "Y" strainer, 1 1/2"
20. Nicholson Steam Trap, 1 1/2" # 5718100
21. Kunkei 3/4", 75 PSI, Steam Safety Relief Valve #6030ED
22. Magnatrol 1" Blowdown Valve #116SR44
23. "Optional" Parker Condensate Cooler #V47AC-3
24. M-C Name plate, with Model No. and Serial No
25. Switch 52SC6AX w/contacts
26. Key Start Switch, 2 poss. spring

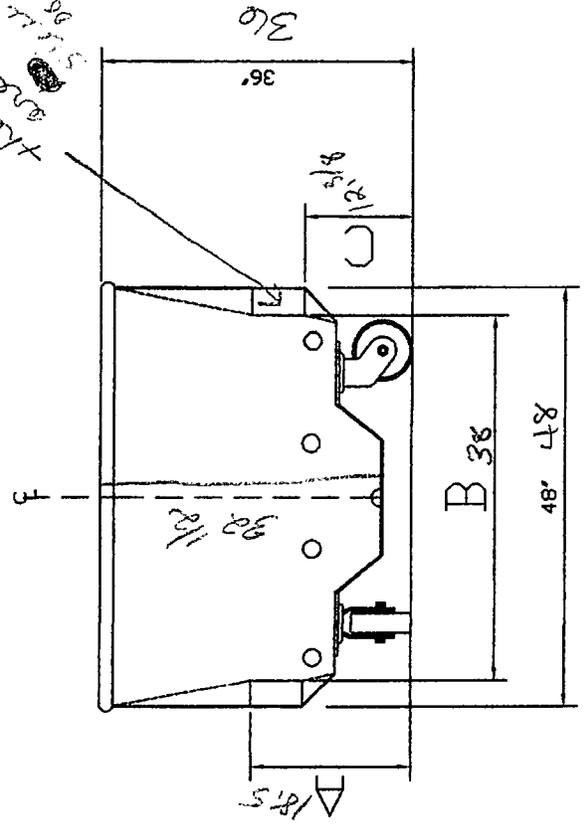


The Mark-Costello Co. sterilizers parts breakdown does not include door hinge parts, gasket controller parts or Hi-Volume units. NO SCALE

SLEEVE OPENING-DIMENSIONS
(FOR USE WITH HYDRAULIC CART DUMPER)



SIDE VIEW



END VIEW

Handwritten notes:
 + Holts
 all right
 36
 36
 92 lbs
 18 1/2
 48

A 18 1/2
 B 38
 C 125/8

initials: _____

HIGH VOLUME STERILIZER CARTS SLEEVE OPENING-DIMENSIONS	
DR. MK	CAD.
CK.	APP.
DATE: 11-29-06	
SCALE: AS SHOWN	
TOL: + - 1/16	
DRAWING NO. 1106-021	
WWW.MARK-COSTELLO.COM	

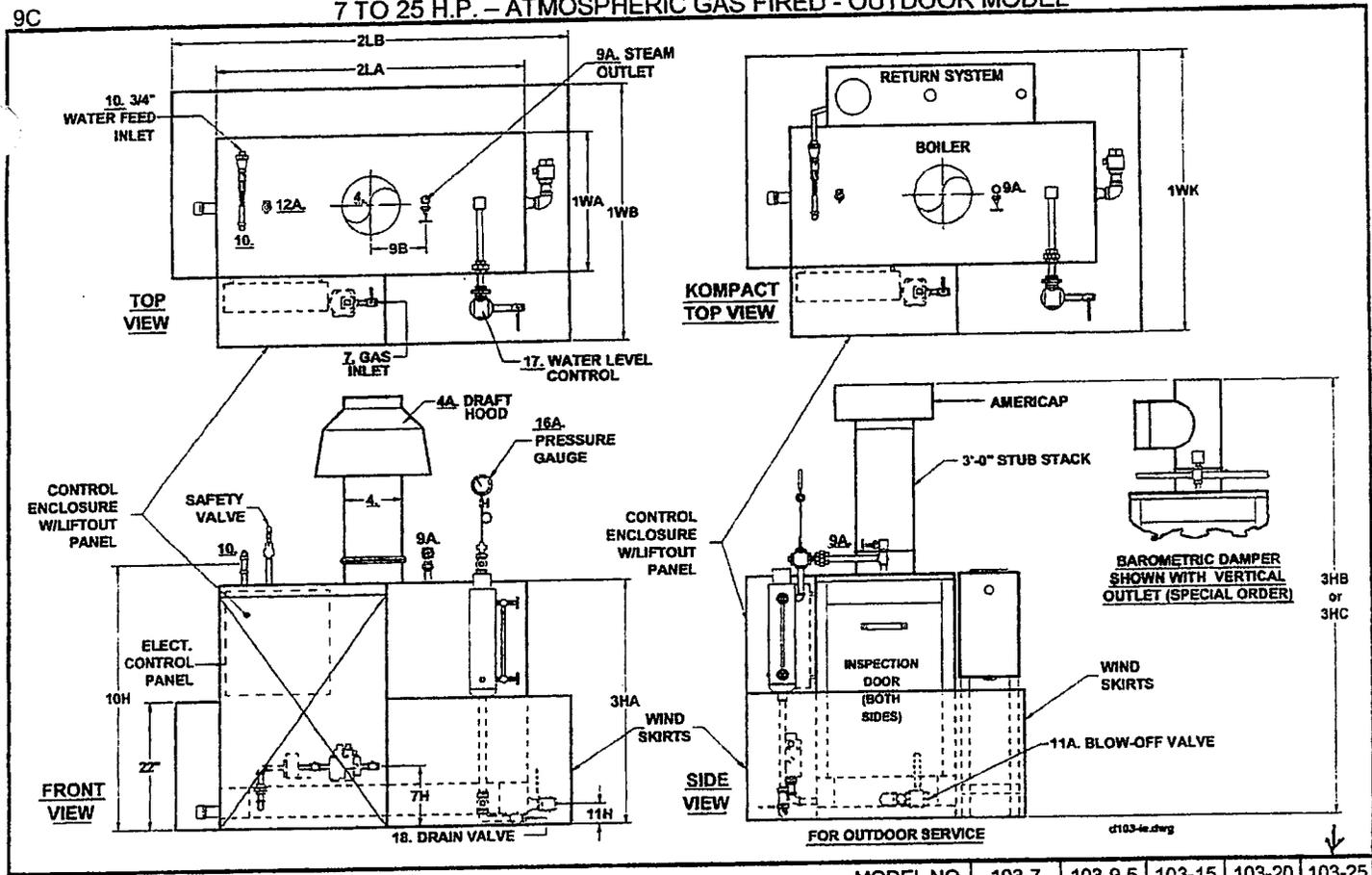


MARK-COSTELLO CO.

Boiler Specs

SPEC. SHEET D-103-IE
9C

PARKER INDUSTRIAL HORIZONTAL DRUM STEAM BOILER 7 TO 25 H.P. - ATMOSPHERIC GAS FIRED - OUTDOOR MODEL



		MODEL NO.	103-7	103-9.5	103-15	103-20	103-25
		HORSEPOWER	7 HP	9.5 HP*	15 HP	20 HP	25 HP
A	BTU Input	1000's BTU/HR.	301	398	645	860	1075
B	BTU Output at rating from and at 212°F	1000's BTU/HR.	241	318	516	688	860
C	Heating Surface	SQ. FT.	47	68	82.5	106	132
D	Rated Steaming Capacity from and at 212°F	LBS./HR.	242	328	518	690	863
1WA	Width Cabinet Only	IN.	21	24	27	30	36
1WB	Width Overall Including Wind Skirts	IN.	41	44	47	50	56
1WK	Width Parker Kompact - (Boiler With Return System) Including Wind Skirts	IN.	45	48	51	57	63
2LA	Length of Cabinet Only	IN.	42	53	53	61	62
2LB	Length Overall Including Wind Skirts	IN.	57	68	69	76	78
3HA	Height of Cabinet Only	IN.	42	42	42	46	46
3HB	Height Overall Including Draft Hood - (Std.) 3'0" Stub Stack & Americap (approx.)	IN.	72/89	74/91	76/93	82/100	82/100
3HC	Height Overall Including Barometric Damper (Vert. Outlet/Horizontal Outlet)-(Spec. Order)	IN.	58/55	61/59	64/61	68/65	72/68
4A	Vent Stack Diameter with Draft Hood - (Standard)	IN.	8	10	12	14	14
4B	Vent Stack Diameter with Barometric Damper - (Special Order)	IN.	6	8	10	10	12
7A	Gas Inlet Size - Standard Nat. Gas/ Supply Press. Min: 7" WC; Max: 14" WC	IN.	3/4	3/4	1	1-1/2	1-1/2
7A1	Natural Gas Manifold Pressure at Burner	IN. WC	4	4	4	4	4
7B	Gas Inlet Size - High Press. Nat. Gas & Propane Gas / Supply Press. 1-5 PSI	IN.	3/4	3/4	3/4	1-1/2	1-1/2
7B1	Propane Gas Manifold Pressure at Burner	IN. WC	18	18	18	18	18
7H	Gas Inlet Height From Floor	IN.	11	11	12	13	13
9A HP	Steam Valve Size - High Pressure 60 to 250 PSI	IN.	3/4	1	1	1	1-1/4
9 LP	Steam Outlet Size - Low Pressure 15 PSI or less - (Special Order)	IN.	1-1/2	2	2	2	2-1/2
9B	Steam Outlet Location - From Center of Boiler	IN.	7	9	9	12	12
10H	Water Inlet Height From Floor	IN.	45	45	45	50	50
11A	Blow-off Valve Size	IN.	1	1	1	1-1/4	1-1/4
11H	Blowdown Line Height From Floor	IN.	3	3	3	3	3
12A HP	Safety Valve Drain Size - High Pressure - 100 PSI - Standard	OUTLET IN.	1	1	1	1-1/4	1-1/4
12A LP	Safety Valve Drain Size - Low Pressure - 15 PSI ("H" Code)- (Special Order)	OUTLET IN.	3/4	1-1/2	1-1/2	1-1/2	2
18	Water Column Drain Valve Size	IN.	3/4	3/4	3/4	1	1
J	Net Weight Of Boiler	LBS.	910	1205	1400	1820	2095
K	Domestic Crated Shipping Weight of Boiler	LBS.	1055	1360	1555	2000	2325
	Same with Return System or Kompact Mounting	LBS.	1350	1650	1850	2360	2865

MINIMUM LISTED CLEARANCES TO COMBUSTIBLE CONSTRUCTION: 12" Cabinet Sides & Rear, 48" Cabinet Top, 6" Draft Hood Vent Connector, 12" Baro. Damper Chimney Connector

Recommended Clearances for Access: Inspection Doors 18"; Controls 24"; Electrical Panel 30"; Additional Space may be required by Local Codes

NOTE: Dimensions are for 9.5 H.P. except: 430MRTI/Inlet; 344MRTI/Outlet; 340 Lbs./Hr., 1" Low Pressure Nat. Gas Inlet Size.

PARK BOILER CO.
BOILER ROOM FLOOR PLAN SPECIFICATION SHEET
HORIZONTAL DRUM GAS FIRED STEAM BOILER 7-25 H.P.

(A) RECOMMENDED BOILER ROOM SIZE, SINGLE BOILER, ATMOSPHERIC GAS FIRED:									
NO.	ITEM	7 H.P.	9.5 H.P. ****	15 H.P.	20 H.P.	25 H.P.			
A	Boiler Room Size (Recommended I.D. Width x Length x Height)	7' x 8' x 9'-1/2"	7' x 9' x 9'-1/2"	7'-1/2' x 9' x 9'-1/2'	8' x 10' x 10'	8'-1/2' x 10' x 10'			
D1	Door No. 1 (Width x Height)	3'-1/2' x 7'	4' x 7'	4' x 7'	4'-1/2' x 7'	5' x 7'			
D2	Door No. 2 (Width x Height)	2'-1/2' x 7'	2'-1/2' x 7'	2'-1/2' x 7'	2'-1/2' x 7'	2'-1/2' x 7'			
AO *	Air Openings - Total Free Area	301 sq. in. *	398 sq. in. *	645 sq. in. *	860 sq. in. *	1075 sq. in. *			
WIF	Width in Front	39"	36"	40"	40"	40"			
IWA	Width Boiler Cabinet	21"	24"	27"	30"	36"			
WIR	Width in Rear	24"	24"	23"	26"	26"			
LOL	Length on Left	24"	24"	24"	26"	26"			
2LA	Length Boiler Cabinet	42"	53"	53"	61"	62"			
LOR	Length on Right	30"	31"	31"	33"	32"			
3HA	Cabinet Height	42"	42"	42"	46"	46"			
4A	Vent Stack Diameter with Draft Hood (Standard)	8"	10"	12"	14"	14"			
4B	Chimney Stack Diameter with Barometric Damper (Special Order)	6"	8"	10"	10"	12"			
7A	Gas Inlet Size - Standard Natural Gas	3/4"	3/4"	1"	1-1/2"	1-1/2"			
7B	Gas Inlet Size - High Pressure Natural Gas and LPG Gas	3/4"	3/4"	3/4"	1-1/2"	1-1/2"			
7C	B.T.U. Input required at rating	301,000	398,000	645,000	860,000	1,075,000			
9A HP	Steam Outlet Size - High Pressure	3/4"	1"	1"	1"	1-1/4"			
9 LP	Steam Outlet Size - Low Pressure	1-1/2"	2"	2"	2"	2-1/2"			
10	Water Inlet Pipe Size to Boiler	3/4"	3/4"	3/4"	3/4"	3/4"			
11	Main Blowdown Line Size	1"	1"	1"	1-1/4"	1-1/4"			
12A HP	Safety Valve Drain Size (100 PSI)	1"	1"	1"	1-1/4"	1-1/4"			
12A LP	Safety Valve Drain Size (15 PSI)	3/4"	1-1/2"	1-1/2"	1-1/2"	2"			
18	Water Column Drain Size	3/4"	3/4"	3/4"	1"	1"			
22	Return Tank Size (Width x Length x Height)	10" x 36" x 42"	10" x 36" x 42"	10" x 36" x 42"	13" x 36" x 46"	13" x 36" x 46"			
23 **	Return Line Inlet Size	1-1/4" **	1-1/4" **	1-1/2" **	1-1/2" **	1-1/2" **			
26	Return Tank Water Inlet Line Size	1/2"	1/2"	3/4"	3/4"	3/4"			
27A	Return Tank Vent Size Required	1"	1"	1-1/4"	1-1/4"	1-1/4"			
27B	Return Tank Vent with Dry Cleaning Steam Vacuum	3"	3"	3"	3"	3"			
28	Return Tank Overflow	1"	1"	1"	1"	1"			
29	Return Tank Drain Line Size	3/4"	3/4"	1"	1"	1"			
30	Blowdown Tank Size (Diameter x Height)	12" x 66"	12" x 66"	16" x 68"	20" x 71"	20" x 71"			
32	Blowdown Tank Vent Outlet Size	2'-1/2"	2'-1/2"	2'-1/2"	3"	3"			
32L ***	Minimum Reduced Vent Line Size for up to 150 PSI	2" ***	2" ***	2" ***	2'-1/2" ***	2'-1/2" ***			
33	Blowdown Tank Drain Line Size	1"	1"	1"	1-1/4"	1-1/4"			
FS	Recommended Drain Line Size from floor sump to sewer	2"	2"	2"	2'-1/2"	2'-1/2"			
ES	Electrical Service - Main Line Disconnect Switch	15 AMP	15 AMP	15 AMP	15 AMP	15 AMP			

* Air Opening sizes based on horizontal ducts to outdoors. See GBI 101-5 Paragraph V for complete details.

** Can be decreased on high pressure or close runs. Increase on low pressure or long runs.

*** Consult Local Inspection Authority for approval before reducing Vent Line to size shown.

**** 10 H.P. available with same dimensions as 9.5 H.P. except BTU Input is 430M BTU and Air Openings are 430 Sq. In.

NOTE: All installation dimensions and specifications are adequate for operation of standard equipment. Specs. subject to change without notice. Special equipment may require additional space. All installations must comply with Local Code Requirements.

(IB) MINIMUM RECOMMENDED BOILER ROOM SIZE, SINGLE BOILER WITH RETURN TANK AND BLOWDOWN TANK:									
NO.	ITEM	7 H.P.	9.5 H.P.	15 H.P.	20 H.P.	25 H.P.			
A	Boiler Room Size (W x L x H) I.D.	6-1/2' x 6-1/2' x 7'	6-1/2' x 7-1/2' x 7'	7-1/2' x 7-1/2' x 8'	8' x 8-1/2' x 8'	8-1/2' x 8-1/2' x 8'			
WIF	Width in Front	35"	35"	40"	40"	40"			
WIR	Width in Rear	22"	19"	23"	26"	26"			
LOL	Length on Left	18"	18"	18"	18"	18"			
LOR	Length on Right	18"	19"	19"	23"	22"			
(IC) MINIMUM ALLOWABLE BOILER ROOM SIZE FOR SINGLE BOILER AND RETURN SYSTEM: Blowdown Tank and All Other Equipment Outside Boiler Room									
A	Boiler Room Size (W x L x H) I.D.	6' x 6-1/2' x 7'	6-1/2' x 7-1/2' x 7'	7' x 7-1/2' x 8'	7-1/2' x 8-1/2' x 8'	8' x 8-1/2' x 8'			
(ID) RECOMMENDED BOILER ROOM SIZE, DUAL BOILERS:									
A	Boiler Room Size (W x L x H) I.D.	9' x 11-1/2' x 9-1/2'	10' x 12' x 9-1/2'	10-1/2' x 13' x 9-1/2'	12' x 13-1/2' x 10'	12' x 14-1/2' x 10'			
AO*	Air Openings - Total Free Area	602 Sq. In. *	796 Sq. In. *	1290 Sq. In. *	1720 Sq. In. *	2150 Sq. In. *			
WIF	Width in Front	28"	28"	30"	34"	34"			
WIR	Width in Rear	38"	39"	43"	49"	48"			
LOL	Length on Left	36"	36"	40"	40"	40"			
LBB	Length Between Boilers	38"	38"	40"	40"	40"			
LOR	Length on Right	22"	22"	22"	22"	22"			
22	Return Tank Size (W x L x H)	10" x 36" x 42"	13" x 36" x 46"	30" x 36" x 58"	30" x 36" x 58"	30" x 36" x 58"			
23 **	Return Line Inlet Size	1-1/2" **	1-1/2" **	2" **	2" **	2" **			
26	Return Tank Water Inlet Line Size	3/4"	3/4"	1"	1"	1"			
27A	Return Tank Vent Size Required	1-1/4"	1-1/4"	1-1/2"	1-1/2"	1-1/2"			
29	Return Tank Drain Line Size	1"	1"	1"	1"	1"			
30	Blowdown Tank Size (D x H)	12 x 66"	12 x 66"	16 x 68"	20 x 71"	20 x 71"			

* Air Opening sizes based on horizontal ducts to outdoors. See GBI 101-5, Paragraph V for complete details.

** Can be decreased on high pressure or close runs. Increase on low pressure or long runs.

NOTES:

1. All other dimensions same as those shown under IA on preceding page.
2. In dual boiler rooms, gas main must accommodate twice B.T.U. shown Item 7C on preceding page.
3. Boiler room size may be smaller than shown but will not provide desired accessibility.
4. All installation dimensions and specifications are adequate for proper operation of standard equipment. Special equipment may require additional space. All installations must comply with Local Code Requirements. Specifications subject to change without notice.

Washsmart Specs



WashSmart S6000

Instruction Manual: Section 1

Description of Washsmart System



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System Overview

1.1 Functional Overview

The Washsmart Robotic System is designed to achieve the following:

Automatically open sharps containers and empty contents.

Dispense sharps into a bulk waste bin.

Wash, rinse and dry containers ready for re-use.

The following diagram indicates the flow of container and sharps through the major assemblies of the Washsmart system:

S6000 Process Flow

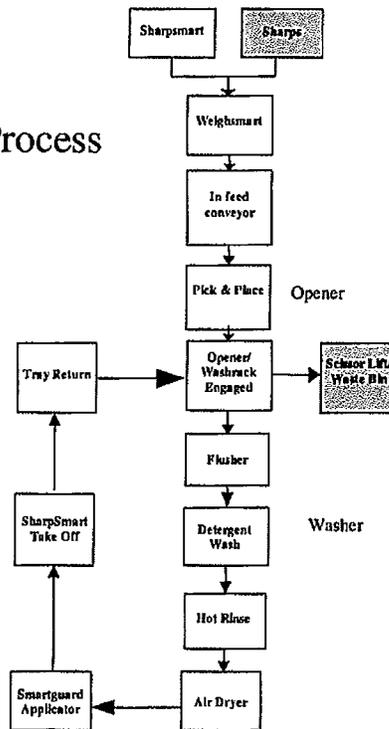


Figure 1 : Container Flow through Washsmart System

1.2 Process Overview

1.2.1 Loading the Containers

The full container is removed from a specially designed transporter and loaded onto the in-feed conveyor to the Opener.

The Washsmart system accommodates 'S' series containers of the following sizes:

Size	Capacity (litres)
Small	15
Medium	22
Large	32
Extra Large	64

Table 1: Container Sizes

1.2.2 Opening & Emptying

1. The container is located by a stop at the end of the in-feed conveyor, ready for the Pick & Place assembly to lift and position the container in the robotic opener. The Pick & Place has been upgraded to encompass the larger S64 collector. This includes an upgrade of mechanical, electrical and pneumatic components.
2. The Opener secures the container and automatically unlocks and opens the container lid.
3. The container is rotated into a raised hopper and sharps contents dispensed into the bulk factory waste bin.
4. The empty container is then transferred along the out-feed conveyor to the Washer.

1.2.3 Waste sharps removal

Once the bulk factory waste bin full, the computer interface (GUI) will read "Bulk Bin Full". The bulk bin is then required to be removed via the scissor lift or ramp and replaced with an empty bin.

1.2.4 The Washing Process

Containers are thoroughly cleaned using a state of the art multistage washing and sanitising system. Stages include:

Flush with 2-6 liters of cold water in 2-second blast, to loosen large solids and separate them into a collection bin.

Detergent wash

Hot (2nd Rinse) to sanitise and thoroughly clean

1.2.5 The Smartguarding Process

1. The applicator stops the wash rack and applies a mist of Smartguard to the interior surfaces and tray area at a temperature of 55°C.
2. Excess Smartguard is removed from the wash rack, by a second set of air knives.

1.2.6 The Air Drying Process

1. The outside and inside of the collectors (still on wash racks) are dried using a series of air knives and nozzles as they are transported on the return conveyor.

1.2.7 Wash Rack Return

1. Washed & dried containers, still on the wash racks are released automatically as they are fed out onto the return conveyor.
2. An operator with clean gloves unloads bins.
3. Wash racks are automatically returned to the Opener for the receiving of another sharps container

1.3 S/C64 Upgrades

1.3.1 Opener & Head:

- A WeighSmart unit has been added to weigh the containers and scan each container's barcode.
- For the pick and place; the vertical and horizontal cylinders, claw assembly and main frame have been upgraded to process the larger S64 containers.
- The head has added linear actuators to open the S64 liners.

1.3.2 Flusher & Washer:

- The paddle switch has been modified to allow for the larger S64 containers.
- The washer manifolds have been raised to allow for the larger S64 containers.
- The Flusher Drawer is now able to be completely removed for increased access for cleaning.

1.3.3 Dryer & Outfeed Conveyor:

- The Spinner has been removed and replaced with an air drying system.
- A tray transfer has been added to transfer the containers (on washrack) from the dryer infeed conveyor over to the return conveyor and smartguard outfeed section.
- The inside of the collectors (still on wash racks) is dried using a blower system as they are transported on the return conveyor.
- The outside of the collectors is dried with a combination of air knives and air nozzles.
- SmartGuard is applied to the interior surfaces of S-64 collectors in the same manner to as a normal S-series collector. Misting nozzles are utilised here for better application.

1.4 Control System Overview

An industrial computer mounted at the Opener in-feed conveyor is used as a graphical user interface. The following functions are accomplished:

Alert the operator of faults by visual indication.

Reset faults.

Initiate system operating modes.

Start and stop machine.

Display and change process settings.

Record and store log data.



Refer Sect. 2, Appendix A: *Washsmart On-Screen Controls* for details on how to operate the interface.

1.5 Safety Systems

The Washsmart system is protected by a number of different electrical and mechanical safety devices.

A short description of those in direct interface with the operator follows:

1.5.1 PLS scanner

Located at the base of the Opener in-feeder, dictates the 'safety zone' during machine operation. If the operator enters this zone (delineated by tape on the floor) the system will shut down.

1.5.2 Emergency Stop Buttons

Located on the computer, jog station, Washer and Dryer control panels, are of the twist to release red mushroom head type on a yellow background. To restore normal operation, all E-stop buttons must be released and **Restart** pushbutton pressed.

1.5.3 Push Button Colors

Operation	Color
E-stop	Red (Mushroom head)
Start	Green
Normal stop	Red
Restart	Blue (illuminated)
Blue flashing	Fault condition

Table 2: Push Button Colors

1.5.4 Status Indicator Lights

Status	Color
E-stop activation	Red
PLS scanner dirty	Amber
Initialised state – (ready to go)	Green flashing
Run mode	Green
Fault condition	Blue flashing
Smartguard tank level fault	Amber

Table 3: Indicator Light Colors

1.5.5 Safety Access Doors

Safety Access Doors are guarded with limit switches and cause an emergency stop condition if opened during operation. Doors are located for:

Access to intermediate conveyor between Opener & Washer.

Each of the washing stages (3 in total).

Dual dryer back doors

Dryer/Applicator internal access.



2 Functional Characteristics

2.1 Services

Service	Unit	Usage (Max)	Comment
Air	7 bar (100 psi)	65 cfm	
Power	415 V @ 60Hz	50 kW/h	
	125 Amp Supply		
Water – Potable		900 l/h, 234 USg/h	
Water – Hot	75°C (167°F)	300 l/h 178 USg/h	
Sewer		1200 l/h, 300 USg/h	3" outlet from m/c
Gas	N/A		
Exhaust		200 l/s (420 cfm)	Air/Steam adjustable
Detergents		20Lt/1500 containers	Elite-Regard (KEM)
Throughput		120 containers/h (max)	Depending on process flow & operator requirements

Table 4: Washsmart Services

2.2 Noise Emissions

The following airborne noise emissions exist for the Washsmart System in the fully operational state:

Criteria No.	Criteria Description	Reading
1	Equivalent continuous A-weighted sound pressure level at work stations. <small>*(refer comments below)</small>	79.3 dB(A)
2	Peak C weighted instantaneous sound pressure value at workstations.	99.0 dB(C)
3	Sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceed 85 dB(A).	N/A <small>reading for criteria 1 < 85dB(A)</small>

Table 5: Noise Emission Readings

* The following schematic indicates the position of operators during the running of the Washsmart system. The peak C-weighted instantaneous sound pressure value of 99 dB(C) results from the impact of sharps when inverted into the waste bucket hopper, which is equidistant from both operators.

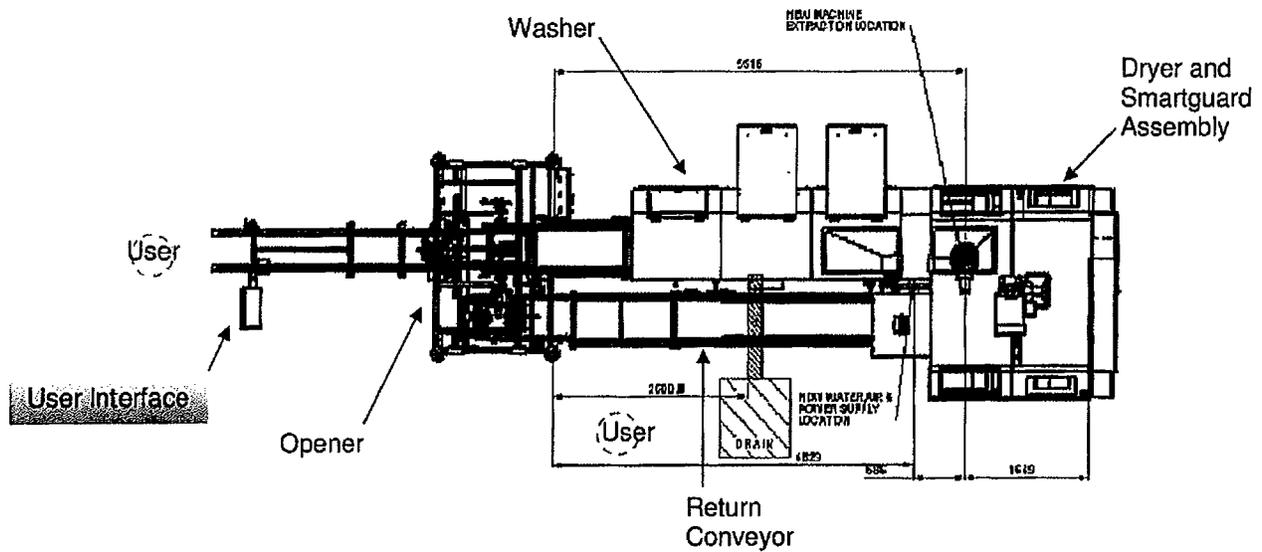


Figure 2: Workstation Locations



3 Equipment Description

3.1 Electrical System

3.1.1 Operating Environment

It is intended that this equipment be connected to a supply voltage of 415 Volts, +/- 10%, 3 phase, neutral and earth. Supply frequency to be generally stable operating at 50Hz +/- 2%.

Full load requirement of the machine is 100 Amps, with upstream fault current limiting to 10kA.

All switch-mode power supplies are capable of maintaining nominal voltage +/- 1% with negligible ripple of 150mV.

All equipment complies with electromagnetic compatibility standards (EN 55011/EN 55014/EN 55022/IEC 801-2,3,4/IEC555-2) and is capable of functioning correctly indefinitely at temperatures between +5°C to +40°C with relative humidity between 30% to 90%. All equipment with an IP rating below IP23 is housed in metal or polycarbonate enclosures to protect against entry of solid bodies or liquids.

3.1.2 Protection Against Electric Shock

Housing most of the electrical equipment in enclosures provides protection against shock. Access to these enclosures is by special tool and deemed for authorized personnel only. In addition, the doors of these enclosures can only be opened when the isolator is in the off position.

3.1.3 Equipment Protection

3.1.3.1 Overcurrent Protection

The end user is to provide fuses or a circuit breaker to protect the supply cable to the machine.

All A.C. circuits are protected by adequately rated circuit breakers or, in the case of larger kW pumps, motor protection devices. Fuses protect extra low voltage circuits.

3.1.3.2 Motor Protection

Overspeed, in the case of Waste Bucket VSD failure, will not cause a hazardous situation. Provision has been made for a mechanical over-travel stop to halt the moving arm keeping it within the guarded area.

Overload is monitored on all motors above 0.5kW by specific motor protection devices that are set to the correct full load current of the motor that they protect. Motors below 0.5kW are fused and internal over-temperature sensing devices provide additional protection.

3.1.3.3 Abnormal temperature Protection

Over-temperature is monitored in all heating circuits.

Two methods are employed:

- In the case of the Rinse heat exchanger, which is short time rated, and which could lose its cooling medium, an over-temperature switch is used.
- In the case of the Applicator, Eco-rinse and Wash tanks high temperature monitoring, a temperature control RTD is used.

3.1.3.4 Supply Interruption

Power loss will not create a hazardous condition therefore no voltage monitoring system has been employed. The machine will go through a power up reset to re-initialise itself upon the return of power.

3.1.4 Bonding/Earthing

3.1.4.1 Protective Bonding Circuit

The tunnel Washer and Dryer frame are connected to the main earth bar located in the Washer electrical cabinet.

All earthing conductors are copper and identifiable by green/yellow insulation.

Partial disassembly will not interrupt the continuity of the protective earth system as earthing does not rely on the interconnection of framework.

Heating elements are not directly earthed, relying on the earthed tank for continuity.

All connection points other than the PE connection are identifiable by the green and yellow bicolor combination.

3.1.4.2 Insulation Failure

One side of the safety step-down transformer has been connected to the protective earth system directly at the secondary terminal, this conductor has been identified as 24N and is used as the common for the 24Vac control. The common for the 24Vdc control is also bonded to earth and is identifiable as -AX.

The Belden data cabling and RTD sensor cables have their shielding bonded to an earth terminal to help eliminate disturbances.

A special shielded cable has also been used between the VSD and the Waste Bucket motor. This cable shield is connected at the Opener electrical cabinet to the earthed gear tray and to the earth stud on the motor. Furthermore, the cable is installed in a PVC sheathed flexible metal conduit that is also earthed by means of a metal gland at the cabinet.

3.1.5 Control Circuits

3.1.5.1 Supply

The Washer & Dryer cubicle utilizes a safety transformer on all outputs and switch-mode power supply for all inputs. The Opener uses a separate switch-mode power supply for both inputs and outputs.

24Vac is used solely for outputs and 24Vdc is used for inputs.

3.1.5.2 Protection against failure

Upon power failure or disturbance the emergency stop system will cut all power to the motors and disconnect air supply to the machine.

Several steps have been taken to minimise risk in the event of a failure.

1. Connection of one side of the control circuit to the protective earth.
2. Switching all active conductors to controlled equipment.
3. Redundancy in the emergency stop circuit and associated contactors.
4. Subsequent stopping of the machine due to the complete removal of power to hazardous equipment.

In the event of earth fault, as one side of the control circuit is bonded to the protective earth, the relevant fuse or circuit breaker will trip. The signaling element of the tripped device will then trigger the machine to stop.

Should a voltage interruption occur the emergency stop circuit would disconnect power to all motors and isolate the air circuit, thus disabling the machine.

3.1.6 Control Interface

3.1.6.1 Input & Outputs

A visual indication of digital inputs and outputs is possible by viewing the eight LED indicators on each module. If the module has sixteen inputs a selector switch enables the user to switch between each set of eight inputs. Network communication cards also have visual indication to help verify healthy transmission status.

The PLC activates two slave relays providing digital run signals to the Hitachi variable speed drive, thus providing isolation between the PLC and the VSD.

An industrial computer mounted at the in-feed conveyor is used as a graphical user interface. Its primary function is to alert the operator of faults by visual indication. The operator is also able to reset faults, initiate machine operating modes and start the machine from this interface. It does not directly control the sequencing or any safety function on the machine and if disconnected would not impede machine operation.

3.1.6.2 Communications

A Modbus to Asi gateway is used to access digital I/O located on the two-wire Asi bus.



A barcode reader connected to the industrial computer is used to log daily throughput and identification of containers.

An RS422 data link operating at 9600 baud interconnects the Washer and Opener PLCs with the industrial computer via a network isolator card.

An RS232 data link operating at 9600 baud interconnects the Opener PLC with the Modbus to Asi gateway module located next to the PLC via a RS232 to RS485 converter immediately adjacent to the PLC.

An RS232 data link operating at 9600 baud interconnects the barcode reader and the industrial computer.

3.1.7 Electronic Programmable Equipment

Program memory is stored in non-volatile flash EPROM and therefore does not require battery backup. An unauthorised person cannot gain access to the program via any switch or keypad on the PLC. The program is well protected, as special software and communications lead is required to access the program in order to make any modifications.

The programming is achieved using the Directsoft programming package and a communications lead.

The current PLC program can be checked using the Directsoft programming package. Each time connection is made to the PLC the software package automatically verifies the existing PLC program against a copy stored on hard disk. Alternatively visual indication of the program could be checked against a printed copy of the program.

3.1.8 Electrical enclosures

The equipment connected to supply voltage has been grouped separately from control voltage devices. Supply and control terminals outside the electrical cabinet are housed in separate junction boxes. Terminals within the cabinets are segregated and can be easily identified by both cable color and markings.

The following ratings apply:

Electrical Equipment	Rating
Electrical enclosures	IP54 as a minimum
Opener motors	IP23
Washer motors	IP65
Spinner/Applicators motors	IP65

Table 6: Electrical Ratings

Enclosures have been installed according to the manufacturer's recommendations, utilising the appropriate fixing accessories so as not to impair the enclosures IP rating. Door and enclosure penetrations to accommodate switches and glands do not impair the IP rating because the openings have been cut in accordance with the switch manufacturers recommendations. The switches and glands are also rated to a higher degree than IP54.



3.1.9 Conductors and cables

All supply and control wiring external to the control cabinets are either PVC/PVC double insulated or PUR double insulated. All supply and control wiring has VDE approval, VDE-Reg. No. 7030.

All supply and control cable conductors are of fine stranded copper. All supply and control cable insulation is PVC designed to operate at a nominal voltage of 300/500V and tested to 4000V.

The use of 0.75mm conductors as a minimum to all motors under 100W, other motors wired according to current capacities

3.1.10 Wiring Practices

3.1.10.1 Connections & Routing

Terminals used are suitable for connection of two or more conductors. Bootlace ferrules are used to as a means of retaining conductor strands in terminals not designed with an integral clamp.

Cable runs are continuous and there are no joints other than at documented junction boxes. This aids the disconnection and subsequent disassembly of the machine for transport purposes.

Supply and control cables operating at different voltages are laid together. These cables have insulation rated at the highest voltage to which any conductor will be subjected.

3.1.10.2 Identification of conductors

Permanent wire numbers are attached to cable cores to identify wiring. Color coding is not generally utilised for cable marking on this machine.

All protective earth conductors are easily identifiable by the green and yellow bicolor combination along the full length of each conductor.

The neutral conductor is identifiable by the use of permanent marking tags at both ends of the conductor labeled "N".

Color	Description
BLACK	a.c. power circuits
BLUE	d.c. control circuits

Table 7 : Wiring Color Coding

3.1.10.3 Wiring inside enclosures

Generally all internal wiring is enclosed within slotted PVC ducting. Cabling extending to the door has been bound together in a spiral wrapping PVC and secured at both ends using cable ties. All wiring that extends outside the enclosure is connected to terminal blocks.

3.1.10.4 Wiring outside enclosures

Cables entering the enclosure shall do so through appropriate glands so as not to reduce the degree of protection afforded to the enclosure.

The "C" channel frame has been utilised as a duct by fitting a suitable cover to enclose wiring, in other areas, where more than 300mm of cable is exposed, PVC covered metal sheathed conduit has been employed as a means of mechanical protection.

The Opener has several areas that are deemed to constitute moving elements, namely the pick and place assembly and the wash rack transfer mechanism. Movement rated flexible cable, classification class 6, has been utilised in these areas. They are adequately supported by the use of drag chains and firmly fixed at each end to avoid any strain on the connection points. These cables and drag chains are so installed to protect the cables against any mechanical damage.

The Dryer/Applicator has one area that constitutes moving elements, the transfer mechanism. The same movement rated flexible cable, classification class 6, has been utilized in these areas. The cables are also supported by the drag chain, which will protect the cables against any mechanical damage.

All interconnection between machine mounted devices is achieved through terminals on the respective cabinet to aid fault finding and testing.

Terminal boxes have been fitted to aid dismantling the machine for shipping. The Opener in-feed is removable, as is the interconnecting wiring between the Washer, Opener, Dryer and Air-Stripper.

Some spare conductors have been installed to various parts of the machine; however, it would be quite easy to run replacement cables throughout the machine.

3.1.10.5 Ducts, connection and junction boxes

No metal conduit or ducts have been used on this machine

The use of PVC covered flexible metal conduit meets the requirements as do the fittings used to terminate.

All connection boxes are readily accessible, are insulated and carry a minimum rating of IP65. Terminals used are mounted on DIN rail and cables enter through glands to maintain the enclosure's integrity.

The boxes only enclose cables and connections for the motor or associated brake. The rating of these boxes has been maintained by the use of proper glands and fittings.

3.1.11 Electric Motors

Any motor over 0.5kW has an overload set to the full load current of the motor.

There are no d.c. motors on this machinery.

Each motor regardless of size has an individual circuit breaker for over-current protection.

The minimum IP rating of motors is IP23, additional protection in the Washer is provided to IP54.



All motors carry a nameplate identifying the manufacturer, size, current rating and voltage. Connection details, where deemed necessary are also detailed as is the IP rating.

Overloads are of the manual resetting type, accessible only after isolating the relevant cabinet to gain access behind cabinet doors.

3.1.12 Warning signs and Item Designations

All electrical equipment is marked with the supplier's name and part number. Each component of the overall machine has a nameplate attached detailing its supplier and part number. In addition, the Washer nameplate also details the power requirements for the total machine.

Warning signs are located on the Washer and Opener electrical cabinets to clearly identify the hazard. The laser safety scanner and barcode scanner also have signs to indicate the presence of a laser hazard.

All control devices have their function clearly and durably marked adjacent to their operating head.

A nameplate is affixed to the inside of each electrical cabinet, the manufacturers name and machine serial number can also be found here. The rated voltage, number of phases and full load current of the supply are also detailed.

The electrical cabinets house various electrical components, all of which are clearly marked to match the designations on the schematics.

3.2 Pneumatic Systems

3.2.1 Overview

The Washsmart system is supplied with compressed air at the Opener and Dryer/Applicator.

A filter regulator is fitted to remove water and maintain a 6 bar supply pressure on the Opener, Washer and Dryer/Applicator. A lubricator is fitted on the Opener supply to lubricate air for protection of downstream pneumatic components.



A pressure switch to shut down the system is set at 5 bar. To ensure reliable operation, maintain air supply at an optimum pressure of 6 bar.

Isolation is achieved with a shut off/safety lock out valve that is manually actuated and bleeds air from the downstream (machinery) side.

The system is designed with two main air supplies to the Opener head and Dryer/Applicator.

To maintain vacuum in the Opener and prevent the sharps container from falling, this air pressure is maintained when an E-stop is activated.

Operation of pneumatic fittings can be manually adjusted with flow control valves.

Pneumatic cylinders have pistons fitted with permanent magnets allowing for non contact sensing by proximity switches of intermediate and end position of the drive.

3.2.2 Opener

3.2.2.1 Pneumatic Control

Directional control of flow with pneumatically powered pilot valves is achieved by valve assemblies actuated by nodes communicating through Asi cables. Each module contains 4 valves with varying configurations to accommodate control flow requirements.

3.2.2.2 Vacuum Generation

Vacuum for suction cups is created by vacuum generator using compressed air flow based on the venturi principal. Various pneumatic components such as control valves, switches and sensors are specifically designed for use with vacuum.

The vacuum generator when de-energised, discharges a small amount of pressurised air aiding in the release of the container from suction cups.



Vacuum fittings are generally denoted with type designation beginning with a 'V'.

3.2.2.3 Rotary Actuators

Rotary actuators generate rotary movement through a shaft or flange using compressed air on the forward and return strokes. Sensing of the end position is possible with additional components and proximity switches.

3.2.2.4 Impact reduction

To prevent damage to the equipment on re-initialisation, a start up valve produces gradual pressure build up. Further protection is given by hydraulic shock absorbers at the end stroke of all moving assemblies.

3.2.3 Washer

Air is directed to the Washer where 3 solenoid valves pneumatically supply the Wash, and Rinse tank solenoid dump valves, and a single solenoid valves pneumatically control the flusher section.

An inductive type proximity switch, inside the washer, starts the flusher pneumatic sequence. The switch is set up to signal when the wash rack is in the correct position.

3.2.4 Dryer/Applicator

Supply from the factory main air supply connects to the main connection plate and an air line runs internally (within the frame) to the main air panel located at the rear of the Dryer.

The main air panel has a filter and isolator, which then supplies a 'T' piece that feeds the air knives and start-up valve.

The Dryer/Applicator start up valve, feeds air into the main manifold which supplies the rest of the air system including the Smartguard applicator.

4 Operational Description

4.1 Opener

 Refer figure 1 & 2, Appendix A

4.1.1 PLS Scanner

The PLS scanner is an optical sensor which scans its surroundings with infrared laser beams. It requires neither separate receivers nor reflectors, giving the following advantages:

Hazardous area is freely accessible.

Hazardous area can be changed by reprogramming software to accommodate existing machinery (i.e. the Opener).

The sensor operates on the principle of reflex time measurement. It emits very short light pulses and at the same time an electronic stopwatch runs. If the light encounters an object, it is reflected back to the sensor. From the time between sending and receiving, the sensor calculates the distance from the object.

In the sensor a rotating mirror deflects the light pulses such that they sweep a semicircular area. By determining the mirror angle, the PLS detects in which direction the object is located.

Given distance and direction of the object, the sensor can determine its precise position.

4.1.2 In-feed conveyor

 Refer figure 2, Appendix A

The in-feed conveyor feeds the Opener with full sharps containers. It must be located and secured before operation can commence.

The conveyor is operated with GO/STOP buttons located at the operator end.

A bar code reader scans the container and relays this back to the control computer for data logging.

The container is then detected and located by a stop at the end of the in-feed conveyor, ready for the Pick & Place.

4.1.3 Pick & Place

 Refer figures 4-7, Appendix A

The following sequence of events occurs during the normal operation of the Pick & Place.

	Sequence of events for the Opener Assembly are given for reference only, many of the steps occur concurrently relying on multiple control conditions being satisfied.
---	---

1. Pick & Place lowers and lifting hooks move in towards the container.

2. Container is raised by Pick & Place.
3. Devac system releases potential vacuum in the container (Standard S-Series only)
4. Pick & Place traverses to Opener position and container front latch is opened (Latches opened on Standard S-Series only).
5. Pick & Place lowers & releases container into the Opener Head.
6. Opener Head vacuum engaged & Pick & Place releases container.
7. Pick & Place raises and traverses back to container pick-up position.

4.1.4 Opener Head

 Refer figures 8-19, Appendix A

The function of the Opener Head is to empty sharps from the container into the Waste Bucket. Sequences of events are:

1. Once the container is released from the Pick & Place, it is secured by vacuum in the Opener Head.
2. Side latches are opened.
3. Lid rotating arm rotates and engages container with vacuum.
4. Lid rotating arm partially opens to the lid 45 degrees.
5. Liner & key rotate bars inserted (For S64, liner and S64 liner bars are inserted).
6. Key rotate opened, releasing liner from container.
7. Container lid is opened fully.
8. Key rotate retracted from container.
9. Lid rotate arm opens fully.
10. Key-rotator closes and retract.
11. Liner rotated out from container.
12. Liner latch extends to secure liner in position.
13. Liner rotate arms close.
14. Container rotated and inverted emptying sharps into Bulk waste bin.



An external air nozzle directs air onto the liner to keep it in the open position.

When the wash rack clears the Opener head and it is conveyed to the Washer by the 90° conveyor:

15. Opener head rotates back to the home position.

4.1.5 Wash Rack Return

 Refer figures 3 & 17–19, Appendix A

Following on from the Opener sequence, the Wash Rack Return completes the following steps:

1. Wash rack is fed by conveyor and located in gripping mechanism.
2. Gripper (toggle clamp) engages and lifts wash rack.
3. Wash rack traverses to the load position.
4. Gripper releases and positions wash rack.
5. Out-feed conveyor raises to engage container with wash rack.
6. Container vacuum released.
7. Liner latch cylinders retracted.
8. Wash rack driven out to Washer as out-feed conveyor lowers.
9. Gripper returns to wash rack pick-up position.

4.2 Scissor lift and Pit

Once full the bulk waste bin is required to be removed from the pit.

To achieve this, the following occurs:

1. Bulk bin is manually retracted onto the scissor lift.
2. The scissor lifts the bulk bin to ground level.
3. After the safety gates are opened the bulk bin can be removed.
4. An empty bulk bin is then loaded onto the scissor lift and lowered.
5. Bulk bin is manually pushed buck under the opener head.

Both the factory waste bin sensor (determines if bin is present) and ultrasonic sensor above the factory waste bin (determines when the bin is full), will stop operation of the Opener.

4.3 Washer

4.3.1 Tank Fill

All stages apart from the final hot rinse and flush have a tank to supply a pump discharging to spray nozzles.

Tanks require to be filled prior to operation of the machine. This can be done on start-up or automatically through the *Preheat Starting Time* function from the on-screen controls.

Rinse and Wash tanks are filled with alternating hot & cold water with the tank temperature probe signaling three solenoid valves located on both the hot & cold manifolds to control the supply flow.

4.3.2 Tank Drainage

 Refer Figure 36 and 40, Appendix A

Each tank can be drained through a solenoid drain valve to a common discharge pipe at the back of the Washer.

Based on an operational throughput of 150 containers/hour, the following discharge estimates exist:

Stage	Flow Rate(Approx.)
Pre-wash:	<ul style="list-style-type: none"> ▪ 900 litres/hour
Wash:	<ul style="list-style-type: none"> ▪ 50 litres/hour ▪ Overflow of 300 litres to discharge pipe
Rinse:	<ul style="list-style-type: none"> ▪ Overflow to Wash tank of 2 litres/container = 300 litres/hour

Table 8: Washer Tanks Drain Rate

Drainage of tanks depend on the amount of contaminants removed from the container at each stage, hence the Pre-wash stage requires a greater input of fresh water than does the Wash stage. The drainage cycle times depend on re-condensation of steam and efficiency of the steam extraction system. With drainage set to a time base, it is independent of the number of containers processed.

At the end of the shift, by pressing **TANK DRAIN** button on the On-Screen controls, will open the drain tank solenoid valves for 2 minutes to completely empty all the Washer tanks.

4.3.3 Controls

 Refer figure 42, Appendix A

Process controls are:

- All pumps have a motor trip and low flow sensors.
- Each tank has a low level switch to maintain contents and high level switch to stop the filling process.
- Water temperature is maintained through sensing on the Wash and Rinse stages, with Rinse 2 protected with an over temperature sensor.

4.3.4 Conveyor drive

 Refer Figure 31-32, Appendix A

The pawl conveyor is driven by an electric motor with a Mayr torque limiter connected directly to the drive arm.

Separate drives exist for the Washer and dryer/Applicator.

4.3.5 Steam Extraction

 Refer Figure 44, Appendix A

The purpose of the extraction system is to:

- Maintain zone temperatures.
- Remove steam from operating areas outside Washer.
- Recycle hot water to increase energy efficiency.

A hood leading to an extraction fan is located above the Buffer zone. Steam is removed and discharged down a duct to a plenum box at beginning of the Dryer.

Inside the plenum box are two baffles which moderate the steam flow to:

- An extraction fan discharging to atmosphere.
- Steam directed back into the Washer at the Rinse zone.

The plenum box over-hangs the end of the Washer to extract escaping steam from the Rinse stage.

Adjustment of the baffle angles alters the amount of steam back into the Washer cavity and hence the amount of re-condensed hot water into the tanks.

Adjustment of the sliding baffle over the fan intake alter the amount of steam being fed back to the Plenum box.

4.3.6 Flusher

 Refer figures 24-26, Appendix A

4.3.6.1 Bin detect switch

The flusher detects the presence of a container with an inductive proximity switch, mounted to the back wall of the canopy.

4.3.6.2 Flusher

The flusher consists of one high pressure “turbo nozzle” for the interior and flat-fan type nozzles for the tray and collector Lids. These high-pressure nozzles fire during the ‘flushing’ stage while with the flat-fan nozzles oscillate to provide better coverage.

4.3.7 Wash

4.3.7.1 Detergent Dispenser

 Refer Figure 37, Appendix A

A self-contained detergent monitoring and dispensing controller combined with a rinse injector dispenses detergent by sensing through a conductivity probe the concentration of detergent in the Wash tank. If the concentration is low the detergent dispensing unit will pump detergent from a 20Lt pail as required.



A full detergent 20Lt Detergent pail should last approx. 1500 containers.

4.3.7.2 Operating characteristics

Operating temperature 55°C

- Drain:
- 3 seconds every 3 minutes – 50 litres/hour
 - end of shift

- Meshes:
- 1 tilted flat tray
 - 1 mesh bucket
 - 1 mesh cover for pump suction

- Tank inputs:
- Cold water (SV40 supply solenoid)
 - Hot water (SV44 supply solenoid)
 - Drainage from dead zone
 - Pump supply through flow switch to nozzle manifold
 - Detergent hose from Vanguard system
 - Overflow from Eco-Rinse tank

- Tank outputs:
- Pump suction through tank mesh
 - Input to drain solenoid
 - Overflow to discharge pipe

- Controls & Electrics:
- Tank level switch
 - Heating element
 - Temperature probe
 - Detergent concentration probe

4.3.8 Rinse

 Refer Figure 38, Appendix A

The hot rinse operates only when a container is detected. Solenoid valve SV42 opens and hot water at 75°C from an external source is fed into the rinse pump M8.

The rinse pump discharges into the heat exchanger which increases the water temperature to 82 °C before being fed to the rinse nozzles.

4.4 Dryer

 Refer figures 43-51, Appendix A

4.4.1 Dryer Infeed

The wash rack is driven into the dryer over the infeed and intermediate conveyors towards the Tray Transfer area. Once the tray is in place and detected in the tray-transfer blocks, it is transferred to the output conveyor where the collector will pass through the first stage of air-nozzles.

Care must be taken to ensure the nozzles are positioned correctly for optimum drying. The air nozzles mounted over the Tray Transfer must be located as to blow behind and in front of the plastic tray and body of the bin as the tray and collector travel across the tray transfer.

4.4.2 Dryer Outfeed

The tray will pass over another set of nozzles where it will pause over the interior and exterior nozzles. Once through these stages the Smartguard is applied. The trays are detected by “paddle-switches” and proximity sensors which must be kept free of waste material.

4.5 Smartguard Applicator

 *Refer figure 38-42, Appendix A*

4.5.1 Application

As the wash rack enters the Smartguard zone; a pair of misting nozzles are activated by an paddle-switch.

The wash rack will pause after it reaches the end of the outfeed conveyor where the misting nozzles will operate. The nozzle responsible for spraying the trays will only operate if a tray is detected by the roller switch, and not operate at all in 64-Mode. From here the next washrack leaving the Dryer will push the washrack over the SmartGuard area out through the “barn-doors”, ready for removal.

4.5.2 Smartguard tank

 *Refer figures 41, Appendix A*

The Smartguard is kept in a tank and recirculated continually by the pump and by-pass valve. The air and liquid pressures must be monitored for best performance of the nozzles and application. If the pressures are not correct they can be adjusted by the recirculating valve (for the liquid) and air pressure-regulators.

Appendix A

Doc ID: 016722560005 Type: CRP
Recorded: 08/31/2015 at 01:49:12 PM
Fee Amt: \$2,326.00 Page 1 of 5
Revenue Tax: \$2,300.00
Instr# 201500008678
Gaston, NC
Susan S. Lockridge Register of Deeds
BK 4804 PG 393-397

RECORDING FEE None
EXCISE TAX PAID 2300.00

NORTH CAROLINA SPECIAL WARRANTY DEED

Excise Tax: \$2,300.00 Pin # 135942
Parcel Identifier No. 3536775386 Verified by _____ County on the _____ day of _____, 20____
By: _____

Mail/Box to: Thomas G. Jaros, Levenfeld Pearlstein, LLC, 2 North LaSalle Street, Suite 1300, Chicago, Illinois 60602

This instrument was prepared by: William E. H. Creech, Esq. 3130 Fairhill Drive, Suite 108, Raleigh, North Carolina 27612

Brief description for the Index: LT 1, Industrial Pike 51@6

THIS DEED made this 27th day of August, 2015, by and between
GRANTOR GRANTEE

B & D REALTY INVESTMENTS, L.L.C., a Georgia limited liability company
8300 Dunwoody Place, Suite 200
Atlanta, Georgia 30350-3304
DANIELS CHESPAK NC, LLC, a Delaware limited liability company
111 W. Jackson Boulevard, Suite 720
Chicago, Illinois 60604

The designation Grantor and Grantee as used herein shall include said parties, their heirs, successors, and assigns, and shall include singular, plural, masculine, feminine or neuter as required by context.

WITNESSETH, that the Grantor, for a valuable consideration paid by the Grantee, the receipt of which is hereby acknowledged, has and by these presents does grant, bargain, sell and convey unto the Grantee in fee simple, all that certain lot, parcel of land or condominium unit situated in the City of Gastonia, Gastonia Township, Gaston County, North Carolina, commonly known as 1851 Chespark Drive, Gastonia, NC, and more particularly described as follows:

Please see Exhibit A attached hereto and incorporated herein by reference.

The property hereinabove described was acquired by Grantor by instrument recorded in Book 3830, Page 263 and, as corrected in, Book 4641, Page 939. All or a portion of the property herein conveyed does NOT include the primary residence of a Grantor. A map showing the above described property is recorded in Plat Book 51, Page 6.

TO HAVE AND TO HOLD the aforesaid lot or parcel of land and all privileges and appurtenances thereto belonging to the Grantee in fee simple.

And the Grantor covenants with the Grantee, that Grantor has done nothing to impair such title as Grantor received, and Grantor will warrant and defend the title against the lawful claims of all persons claiming by, under or through Grantor, other than the matters set forth on Exhibit B.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Grantor has duly executed the foregoing as of the day and year first above written.

B & D Realty Investments, L.L.C.,
a Georgia limited liability company

By: James E. Brewer
James E. Brewer, Member and Manager

State of: Georgia
County or City of: LIBERTY

I, the undersigned Notary Public of the City or County of Gwinnett and State aforesaid, do hereby certify that James E. Brewer, personally appeared before me this day and acknowledged the due execution of the foregoing instrument by him as Member and Manager of B & D REALTY INVESTMENTS, L.L.C., a Georgia limited liability company, for the purposes stated therein.

Witness my hand and official stamp or seal this 27 day of August, 2015.



Q. Badwan Notary Public
Notary's Printed or Typed Name
Q. BADWAN

Exhibit A

Legal Description

BEING THE FULL CONTENTS OF Lot No. One (1) of Industrial Pike as shown on map or plat thereof made by R & W Engineering and Surveying dated March 29, 1994 and recorded in Plat Book 51 at Page 6 in the Gaston County Registry, to which reference is hereby made for a more full and complete description of said lot by metes and bounds.

Exhibit B

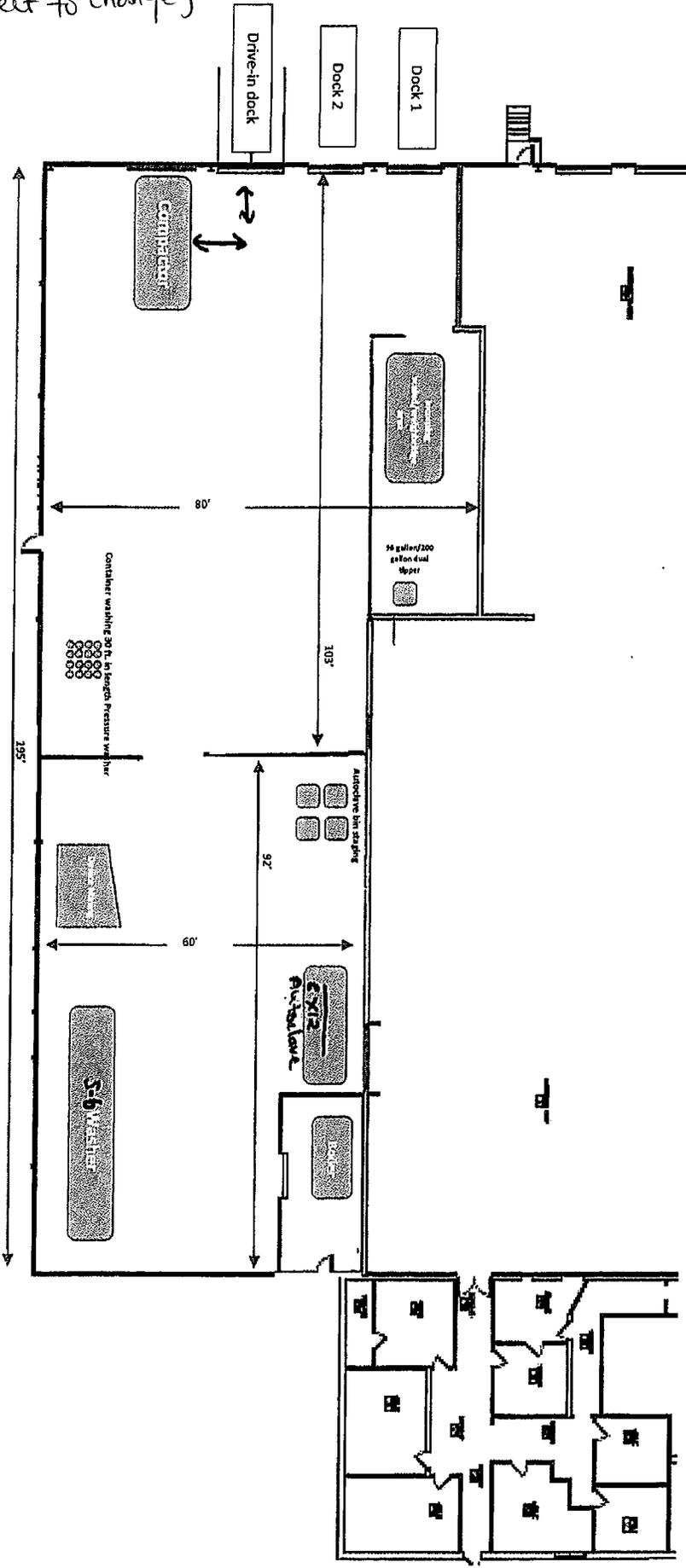
Permitted Exceptions

1. Matters of record not disclosed by that certain Chicago Title Insurance Company Title Commitment No. 15-14868RA, issued by Chicago Title Company, LLC, with an effective date of July 21, 2015.
2. Taxes or assessments for the year 2015, and subsequent years, not yet due or payable.
3. Boundary and property lines reflected on plat(s) recorded in Plat Book 51, Page 6, Gaston County Registry.
4. Any rights, interests or claims which may exist or rise by reason of the following matters disclosed by survey entitled "ALTA/ACSM Land Title Survey for Daniels Health 1851 Chespark Dr. City of Gastonia, Gaston Co., North Carolina" by Steven A. Amos, P.L.S., Trinity Land Surveyors, dated August 27, 2015, signed and sealed August 27, 2015 (the "Survey").
 - a. Electric transformer, utility poles, light poles and overhead utility lines;
 - b. Fire hydrants;
 - c. Sanitary sewer manholes, sanitary clean outs and sanitary sewer lines;
 - d. Catch basins, drop inlets, roof drains, concrete ditches, rip rap ditch and storm drain lines;
 - e. Gas meter and LP tank;
 - f. Chain link fencing with gates;
 - g. Block walls, concrete pads, concrete debris pile and concrete ditches;
 - h. Ten-foot (10') and twenty-foot (20') drainage and utility easements;
 - i. Thirty-foot (30') utility easement;
 - j. Fifty-foot (50') front setback line;
 - k. Twenty-foot (20') and thirty-foot (30') side yard, and twenty-five foot (25') and thirty-foot (30') rear yard, setback lines;
 - l. Approximate location of sediment basin per 1997 aerial photo;
 - m. Chain link fence falls on both sides of the southern property line;
 - n. Encroachment of curb and gutter into the right-of-way of Chespark Drive; and
 - o. Encroachment of adjoiner's ATV path onto the southeastern corner of the Property.
5. Rights of Cynergy Systems, Inc., as occupant party in possession.

Appendix B
 (Subject to change)

Existing
 Space

Approx.
 12,000 sf



Appendix C

Kyle Little

From: Marc Bolick <Marc.Bolick@gastongov.com>
Sent: Tuesday, June 23, 2015 10:00 AM
To: Kyle Little
Cc: 'Jerry Roche'; Jason Kumelski
Subject: Zoning Letter for 1851 Chespark
Attachments: 20150623095827662.pdf

Gentleman,

Attached is the zoning letter for the 1851 Chespark location in Gastonia, NC. Please call me if you have any additional questions.

Regards,



Marc Bolick
Small Business Project Manager
Gaston County Department of Building Inspections
Mobile 704-813-0584
Marc.Bolick@gastongov.com

This message may contain confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete it from your system. Emails that do not contain confidential medical information are subject to North Carolina General Statute, Chapter 132 and may be considered a matter of public record.



June 23, 2015

Daniels Sharpmart, Inc.
Kyle Little
111 W Jackson Blvd, Floor 7
Chicago, IL 60604

Re: Gaston County Tax Parcel 135942
1851 Chespark Drive, Gastonia, NC

Dear Mr. Little:

The City of Gastonia's Planning Department 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 Unified Development Ordinance (UDO), which regulates the use of the subject property.
- 3) The property referenced above is located within the I-2 Exclusive Industrial zoning district.
- 4) The proposed occupancy of the subject property by Daniels Sharpmart, Inc. for the purposes of the collection, device management and treatment of medical waste would be classified as "Manufactured Goods, Class I" by the UDO.
- 5) The use, "Manufactured Goods, Class I", is allowed by right within the I-2 zoning district.
- 6) The Planning Department has no knowledge of any UDO violations associated with the subject property.

Please feel free to contact me at 704 866-6746 with any questions you may have.

Sincerely,

A handwritten signature in black ink that reads "Drew T. Pearson". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

Drew T Pearson, CZO, CFM
Land Use & Zoning Administrator

PO Box 1748
Gastonia, NC 28053
phone 704-866-6746 - fax 704-836-0044
drewp@cityofgastonia.com