MICHIGAN DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENT
AIR QUALITY DIVISION

September 29, 2010

PERMIT TO INSTALL
No. 60-10

ISSUED TO
Daniels Sharpsmart, Inc.

LOCATED AT
5770 Hix Road
Westland, Michigan 48185

IN THE COUNTY OF
Wayne

STATE REGISTRATION NUMBER
P0083

The Air Quality Division has approved this Permit to Install, pursuant to the delegation of authority from the Michigan Department of Natural Resources and Environment. This permit is hereby issued in accordance with and subject to Section 5505(1) of Article II, Chapter I, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended. Pursuant to Air Pollution Control Rule 336.1201(1), this permit constitutes the permittee's authority to install the identified emission unit(s) in accordance with all administrative rules of the Department and the attached conditions. Operation of the emission unit(s) identified in this Permit to Install is allowed pursuant to Rule 336.1201(6).

DATE OF RECEIPT OF ALL INFORMATION REQUIRED BY RULE 203: **August 19, 2010**	
DATE PERMIT TO INSTALL APPROVED: **September 29, 2010**	SIGNATURE:
DATE PERMIT VOIDED:	SIGNATURE:
DATE PERMIT REVOKED:	SIGNATURE:

PERMIT TO INSTALL

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Common Abbreviations / Acronyms

Common Acronyms		Pollutant/Measurement Abbreviations	
AQD	Air Quality Division	BTU	British Thermal Unit
ANSI	American National Standards Institute	°C	Degrees Celsius
BACT	Best Available Control Technology	CO	Carbon Monoxide
CAA	Clean Air Act	dscf	Dry standard cubic foot
CEM	Continuous Emission Monitoring	dscm	Dry standard cubic meter
CFR	Code of Federal Regulations	°F	Degrees Fahrenheit
COM	Continuous Opacity Monitoring	gr	Grains
EPA	Environmental Protection Agency	Hg	Mercury
EU	Emission Unit	hr	Hour
FG	Flexible Group	H_2S	Hydrogen Sulfide
GACS	Gallon of Applied Coating Solids	hp	Horsepower
GC	General Condition	lb	Pound
HAP	Hazardous Air Pollutant	m	Meter
HVLP	High Volume Low Pressure *	mg	Milligram
ID	Identification	mm	Millimeter
LAER	Lowest Achievable Emission Rate	MM	Million
MACT	Maximum Achievable Control Technology	MW	Megawatts
MAERS	Michigan Air Emissions Reporting System	ng	Nanogram
MAP	Malfunction Abatement Plan	NO_x	Oxides of Nitrogen
MDNRE	Michigan Department of Natural Resources and Environment (Department)	PM	Particulate Matter
MIOSHA	Michigan Occupational Safety & Health Administration	PM10	PM less than 10 microns diameter
MSDS	Material Safety Data Sheet	PM2.5	PM less than 2.5 microns diameter
NESHAP	National Emission Standard for Hazardous Air Pollutants	pph	Pound per hour
NSPS	New Source Performance Standards	ppm	Parts per million
NSR	New Source Review	ppmv	Parts per million by volume
PS	Performance Specification	ppmw	Parts per million by weight
PSD	Prevention of Significant Deterioration	psia	Pounds per square inch absolute
PTE	Permanent Total Enclosure	psig	Pounds per square inch gauge
PTI	Permit to Install	scf	Standard cubic feet
RACT	Reasonably Available Control Technology	sec	Seconds
ROP	Renewable Operating Permit	SO_2	Sulfur Dioxide
SC	Special Condition	THC	Total Hydrocarbons
SCR	Selective Catalytic Reduction	tpy	Tons per year
SRN	State Registration Number	µg	Microgram
TAC	Toxic Air Contaminant	VOC	Volatile Organic Compounds
TEQ	Toxicity Equivalence Quotient	yr	Year
VE	Visible Emissions		

* For High Volume Low Pressure (HVLP) applicators, the pressure measured at the HVLP gun air cap shall not exceed ten (10) pounds per square inch gauge (psig).

GENERAL CONDITIONS

1. The process or process equipment covered by this permit shall not be reconstructed, relocated, or modified, unless a Permit to Install authorizing such action is issued by the Department, except to the extent such action is exempt from the Permit to Install requirements by any applicable rule. **(R 336.1201(1))**

2. If the installation, construction, reconstruction, relocation, or modification of the equipment for which this permit has been approved has not commenced within 18 months, or has been interrupted for 18 months, this permit shall become void unless otherwise authorized by the Department. Furthermore, the permittee or the designated authorized agent shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Natural Resources and Environment, P.O. Box 30260, Lansing, Michigan 48909, if it is decided not to pursue the installation, construction, reconstruction, relocation, or modification of the equipment allowed by this Permit to Install. **(R 336.1201(4))**

3. If this Permit to Install is issued for a process or process equipment located at a stationary source that is not subject to the Renewable Operating Permit program requirements pursuant to R 336.1210, operation of the process or process equipment is allowed by this permit if the equipment performs in accordance with the terms and conditions of this Permit to Install. **(R 336.1201(6)(b))**

4. The Department may, after notice and opportunity for a hearing, revoke this Permit to Install if evidence indicates the process or process equipment is not performing in accordance with the terms and conditions of this permit or is violating the Department's rules or the Clean Air Act. **(R 336.1201(8), Section 5510 of Act 451, PA 1994)**

5. The terms and conditions of this Permit to Install shall apply to any person or legal entity that now or hereafter owns or operates the process or process equipment at the location authorized by this Permit to Install. If the new owner or operator submits a written request to the Department pursuant to R 336.1219 and the Department approves the request, this permit will be amended to reflect the change of ownership or operational control. The request must include all of the information required by subrules (1)(a), (b), and (c) of R 336.1219 and shall be sent to the District Supervisor, Air Quality Division, Michigan Department of Natural Resources and Environment. **(R 336.1219)**

6. Operation of this equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. **(R 336.1901)**

7. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal condition or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5). **(R 336.1912)**

8. Approval of this permit does not exempt the permittee from complying with any future applicable requirements which may be promulgated under Part 55 of 1994 PA 451, as amended or the Federal Clean Air Act.

9. Approval of this permit does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.

10. Operation of this equipment may be subject to other requirements of Part 55 of 1994 PA 451, as amended and the rules promulgated thereunder.

11. Except as provided in subrules (2) and (3) or unless the special conditions of the Permit to Install include an alternate opacity limit established pursuant to subrule (4) of R 336.1301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with R 336.1303. **(R 336.1301)**
    a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
    b) A visible emission limit specified by an applicable federal new source performance standard.
    c) A visible emission limit specified as a condition of this Permit to Install.

12. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in R 336.1370(2). **(R 336.1370)**

13. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with R 336.2001 and R 336.2003, under any of the conditions listed in R 336.2001. **(R 336.2001)**

SPECIAL CONDITIONS

EMISSION UNIT SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Emission Unit ID	Emission Unit Description (Process Equipment & Control Devices)	Installation Date / Modification Date	Flexible Group ID
EUAUTOCLAVE	Bondtech Treatment Technology (BTT) Autoclave w/BTT Barometric Spray Condenser Size: 30' length x 6' diameter Capacity: 3600 Pounds/Cycle Add-on Controls: Modified G-3B1000 Air Purification System w/ Sulfur Impregnated Carbon - two drums connected in series Charge: Regulated Medical Waste & Sharps Process steam from the autoclave is evacuated to the condenser, then to the sanitary sewer. After the steam is evacuated, residual emissions from the autoclave, including off-gassing from the waste in the autoclave bins, are captured by a hood mounted over the autoclave door and exhausted through the control system, which is internally exhausted.	September 29, 2010	N/A
EUBOILER	Vapor Corporation (Thermogenics) Model: Circulatic 13.35 MM Btu/hr Natural Gas fired	September 29, 2010	N/A
Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as allowed by R 336.1278 to R 336.1290.			

The following conditions apply to: EUAUTOCLAVE

I. EMISSION LIMITS

1. There shall be no visible emissions from EUAUTOCLAVE when opening the door after the decontamination cycle is complete. **(R336.1901, R336.1910)**

II. MATERIAL LIMITS

1. The permittee shall not treat any waste in EUAUTOCLAVE other than the wastes specified in this condition. **(R 336.1201(3), R 336.1901)**

   The permittee shall not accept or treat any hazardous wastes from facilities classified as small quantity generators or large quantity generators under Part 111 of Public Act 451 of 1994, as amended.

   Medical/Infectious Waste - As defined in the federal Standards of Performance for New Stationary Sources, 40 CFR 60.51c, medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of

biologicals that is listed in 40 CFR 60.51c. The permittee shall not treat any waste in EUAUTOCLAVE specifically prohibited under the Medical Waste Regulatory Act, Part 138, 1978 P.A. 368, as amended.

III. PROCESS/OPERATIONAL RESTRICTIONS

1. The permittee shall not operate EUAUTOCLAVE unless the "Medical Waste Processing and Transfer Facility Operation Manual," which includes the Waste Management Plan (WMP) and Preventative Maintenance/Malfunction Abatement Plan (MAP), specified in Appendix A, or an alternate plan approved by the AQD District Supervisor, is implemented and maintained. If the plan initially developed fails to address or inadequately addresses an event, the owner or operator shall revise the plan within 45 days after such an event occurs and submit an acceptable revised plan to the AQD District Supervisor. The revised plan shall include procedures for maintaining and operating in a satisfactory manner, EUAUTOCLAVE, add-on air pollution control device, or monitoring equipment during the events, and a program for corrective action for such events. **(R 336.1201(3), R 336.1901)**

IV. DESIGN/EQUIPMENT PARAMETERS

1. The permittee shall not operate EUAUTOCLAVE unless the carbon control system is installed, maintained, and operated in a satisfactory manner. **(R 336.1224, R 336.1225, R 336.1702, R 336.1901, R 336.1910)**

2. The permittee shall design and operate the condenser and the condensate receiving and discharge equipment so that no emissions from the condenser or condensate enter the plant environment when discharging to the sewer. **(R 336.1224, R 336.1225, R 336.1702, R 336.1901)**

3. The permittee shall not operate EUAUTOCLAVE unless the mercury saturation indicators are installed, maintained, and operated in a satisfactory manner. **(R 336.1224, R 336.1225, R 336.1702, R 336.1901, R 336.1910)**

V. TESTING/SAMPLING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. The permittee shall collect two samples of the sulfur impregnated carbon from each drum, one near the center and one near the outer wall, for a total of four samples, at least once every six months. The carbon samples shall be analyzed for total mercury content. The testing will continue at this frequency until a carbon drum is replaced. Replacement will occur at breakthrough or when a carbon sample tests at or above 100 ppm of mercury. When breakthrough occurs, the permittee shall not operate EUAUTOCLAVE until the first carbon drum has been replaced. Note that this may be accomplished by moving the second drum into the first position and installing a new drum in the second position. Sampling will begin six months after the carbon replacement and will continue on the previous test cycle. The permittee shall submit any request for a change in the testing frequency to the AQD District Supervisor for review and approval. **(R 336.1224, R 336.1225, R 336.1702, R 336.1901, R 336.1910)**

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. The permittee shall install, maintain and operate in a satisfactory manner a device to monitor and record the time interval, temperature, and pressure of each step in the decontamination process in accordance with the operating parameters listed in the Medical Waste Processing and Transfer Facility Operation Manual referenced in SC III.1. for EUAUTOCLAVE on a continuous basis. **(R 336.1201(3), R 336.1901)**

2. The permittee shall monitor, in a satisfactory manner, the description of waste treated in EUAUTOCLAVE on an as-treated basis. **(R 336.1201(3), R 336.1901)**

3. The permittee shall keep, in a satisfactory manner, records of the decontamination temperature, pressure, time and description of waste treated for EUAUTOCLAVE. All records shall be kept on file at the site and made available to the Department upon request. **(R 336.1201(3), R 336.1901)**

4. The permittee shall monitor, in a satisfactory manner and on a regular basis, the mercury saturation indicator located on the blower discharge of EUAUTOCLAVE. **(R 336.224, R 336.1225)**

5. The permittee shall keep, in a satisfactory manner, records of all regular monitoring and saturation events for the mercury saturation indicator on EUAUTOCLAVE. If the indicator becomes saturated, the permittee may need to modify the carbon sampling schedule in SC V.1. to determine if the saturation indicator is indicating breakthrough. The permittee shall correlate the carbon sampling data from SC V.1. with the monitoring data from VI. 4. and 5 using a recordkeeping format acceptable to the AQD District Supervisor. All records shall be kept on file at the site and made available to the Department upon request. **(R 336.1224, R 336.1225, R 336.1702, R 336.1901, R 336.1910)**

VII. REPORTING

1. N/A

VIII. STACK/VENT RESTRICTIONS

1. N/A

IX. OTHER REQUIREMENTS

1. N/A

APPENDIX A

Medical Waste Processing and Transfer Facility Operation Manual

Daniels Sharpsmart, Inc.

MEDICAL WASTE PROCESSING AND TRANSFER FACILITY OPERATION MANUAL

August 2010

Andrea Arredondo
August 5 2010 (Revised)

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SECTION#

11.0 TRAINING PLAN

12.0 Medical Waste Management Plan

1.0 GENERAL

1.1 Purpose

This plan describes the process for managing Medical Waste at this Facility. It also describes the procedures to comply with applicable Federal, State, and Local Government laws and regulations applicable to Medical Waste.

1.2 Scope

This plan applies to all processes utilized in the management of Medical Waste including acceptance, processing, storage, and transfer of Medical Waste at this Facility.

1.3 Responsibilities

The protocols established in this plan apply to all personnel managing Medical Waste at this Facility.

The *Facility Manager* will assure that 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 and biohazardous wastes are handled, stored, treated, and disposed of properly and safely. They must also provide the equipment necessary to maintain compliance with the Medical Waste Regulatory Act, Part 138 of the Public Health Code.

The facility manager is ultimately responsible for ensuring proper handling, storage, treatment, and disposal of all Medical Waste managed at this facility.

▪

- *Site workers* are responsible for following the instruction of the Site Supervisor concerning handling, storage, process, and transfer of Medical Waste.
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Compliance Manager is responsible for providing guidance, and for monitoring site compliance with mandated Medical Waste guidelines. Compliance is available to provide training when requested.

1.4 Contact Information

1.4.a Primary Contact Person

Facility Manager:

Darren Whitman phone 734-306-8153

1.4.b Backup Contacts

Evan August phone 423-432-1099

1.4.c Emergency or After-Hours Contact

a) In the event of any emergency or perceived emergency, call **911** (on a land line).

b) In the event of any emergency the Operations Manager and the Compliance Manager will be notified within one (1) hour of the incident.

   i) All incidents will be followed-up by a written report to the Compliance Manager within five (5) working days.

c) For any after-hours concerns regarding the facility, contact the 24-hour emergency number 888-952-5580.

1.5 General Facility Operation Descriptions:

Sharps and Medical Waste is brought to this facility from off-site generators by licensed Medical Waste Transporter. The medical waste is off-loaded from trucks and either processed on-site or transferred off site to an approved processor.

1.5.a Hours of Operation

The business is not seasonal and will operate all months of the year. General hours of operation are 24 hours per day, seven (7) days per week.

1.5.b Waste Flow within the Facility

a) The waste is delivered to this facility in boxes, bags or reusable containers.

b) The waste stream (see section 2.0 Types of Waste) is determined and the following process apply:

   i) Waste that is boxed or bagged is separated for either transfer.

      (1) All pathological, and/or chemotherapeutic wastes, and/or any other biohazardous or Medical Waste requiring incineration will be marked with an “incineration only” label.

      (2) All other boxed or bagged waste will be autoclaved on-site.

   ii) Waste in reusable containers is decanted then sorted for transfer.

      (1) Any reusable container utilized for the packaging and shipment of such waste are decanted and washed through the WashSmart system, as described in section 5.0.

      (2) All pharmaceutical waste is brought into the facility in purple topped containers in order to distinguish them from regular sharps waste.

c) Disposal of processed waste. All decanted waste is managed as medical waste and is shipped to a permitted facility for final treatment and disposal.

d) All pharmaceutical; pathological, and/or chemotherapeutic wastes, and/or any other biohazardous or Medical Waste requiring incineration will be transferred to an approved Offsite Treatment Facility.

Section 5.0 describes the ***Washsmart Operations***.

Section 6.0 describes the ***Medical Waste Processing Operations***

Section 7.0 describes the ***Disposal Operations***

Section 8.0 describes the ***Medical Waste Transfer Operations***

1.6 CLEANING AND DECONTAMINATION

a) Daily cleaning will be accomplished to minimize odor and/or potential litter at this facility.

b) Disinfection will be accomplished through the use of a hypochlorite cleaning solution.

c) Frequency of cleaning will depend on usage and the operational environment. There are three distinct operations to be conducted at the facility.

   i) Waste containers will be decanted and waste will be properly stored and transported to an approved Offsite Treatment Facility.

      (1) Cleaning of such operations will be conducted on a daily basis.

      (2) Disinfection of spill, leaks or otherwise potential health hazards will be conducted on an as need basis.

   ii) Washing of the re-usable sharps containers in the Washsmart System. Parts of the Washsmart System in direct contact with Medical Waste and effluent should be cleaned every shift.

      (1) Caution will be used due to the waste containing contaminated sharp items.

iii) Waste will be transferred off-site for proper treatment and disposal.

d) 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:

i) Hot water trigger action hose long enough to reach inside washer and 90 degree conveyor.

ii) Stiff (wire) brushes for cleaning washer filters.

iii) Long handled tongs for picking up sharps.

iv) Long handled brush for sweeping floor.

v) Dust pan and brush.

vi) Reusable hand spray bottle to fill with detergent and water.

vii) Heavy duty waterproof gloves.

viii) Goggles.

e) Decontamination of Reusable Secondary Containers

i) 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.

ii) Approved methods of decontamination include, but are not limited to, agitation to remove visible soil combined with one of the following procedures:

(1) Exposure to hot water of at least 82 °C (180 °F) for a minimum of 15 seconds.

1.7 RECORD KEEPING AND RETENTION

The following logs will be kept for all plant operations (all are covered in DSI Internal SOP 30 Waste Management Logs):

1. Waste Screening Log
2. Unauthorized Waste Log
3. Autoclave QA Control Log
4. Waste Treatment Log
5. Waste Transfer Log
6. 3rd Party Treatment Log
7. Daily Facility Housekeeping Checklist
8. 3M Test – Container QA/QC validation

All shipment tracking documents, treatment records, and other required documentation will be maintained for at least 5 years.

Records of the calibration checks shall be maintained as part of the facility's files and records for a period of five years or for the period specified in the regulations.

2.0 TYPES OF WASTE

This facility accepts, handles, and transfers Medical Waste, Sharps, pharmaceutical wastes, as subject to the Michigan Medical Waste Regulatory Act, Part 138 of the Public Health Code.

Figure 1 provides a decision tree for medical waste acceptance, processing and transfer at this facility as described below.

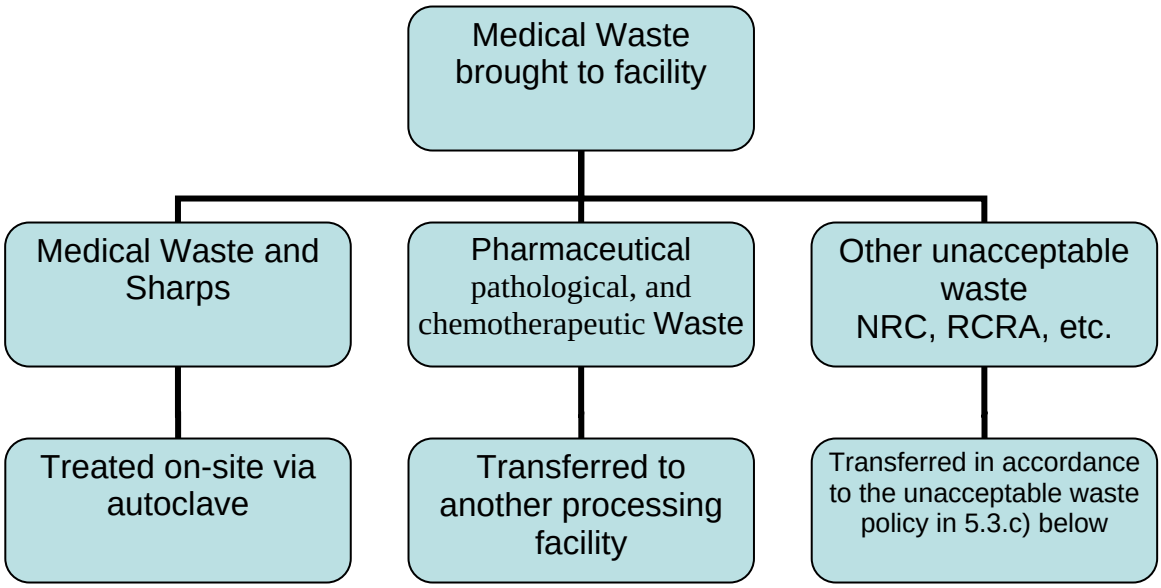

Figure 1 –Medical Waste acceptance, processing and transfer decision tree

2.1 Acceptable Waste:

a) Special Medical waste is municipal and residual waste which is generated in the diagnosis, treatment, immunization or autopsy of human beings or animals, in research pertaining thereto, in the preparation of human or animal remains for interment or cremation, or in the production or testing of biologicals, and which falls under one or more of the following categories:

b) **Cultures and stocks** of infectious agents and associated biologicals, including the following: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines except for residue in emptied containers; and culture dishes, assemblies and devices used to conduct diagnostic tests or to transfer, inoculate and mix cultures.

c) **Pathological wastes.** Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth.

d) **Human blood and body fluid waste.**

i) Liquid waste human blood.

ii) Blood products.

iii) Items saturated or dripping with human blood.

iv) Items that were saturated or dripping with human blood that are now caked with dried human blood, including serum, plasma and other blood components, which were used or intended for use in patient care, specimen testing or the development of pharmaceuticals.

v) Intravenous bags that have been used for blood transfusions.

vi) Items, including dialysate, that have been in contact with the blood of patients undergoing hemodialysis at hospitals or independent treatment centers.

vii) Items saturated or dripping with body fluids or caked with dried body fluids from persons during surgery, autopsy, other medical procedures or laboratory procedures.

viii) Specimens of blood products or body fluids, and their containers.

e) **Animal wastes**. Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens during research (including research in veterinary schools and hospitals), production of biologicals or testing of pharmaceuticals.

f) **Isolation wastes.** Biological wastes and waste contaminated with blood, excretion, exudates or secretions from:

i) Humans who are isolated to protect others from highly virulent diseases.

ii) Isolated animals known or suspected to be infected with highly virulent diseases.

g) **Used sharps.** Sharps that have been in contact with infectious agents or that have been used in animal or human patient care or treatment, at medical, research or industrial laboratories.

h) **Non-hazardous Pharmaceutical Waste**. Expired drugs and other pharmaceutical wastes used in a hospital or clinic setting, which are not defined as Federal Hazardous Wastes. All such wastes are transferred off-site for treatment and disposal.

2.2 Transferred Waste: Pharmaceutical; pathological, and chemotherapeutic wastes, and any other biohazardous or Medical Waste requiring incineration must be transferred to another processing facility.

2.3 Unauthorized Waste. Wastes such as any hazardous waste (RCRA) and any waste regulated by the Nuclear Regulatory Commission cannot be processed at this facility. Such wastes will be managed in accordance with section 4.0.

Figure 2.2 Typical Containers and Waste (Based on Industry Standards)

PROPER MEDICAL WASTE DISPOSAL

						
Regular waste: **Clear or Black Bags**	**Biohazardous Waste:** **Red Bags. Red Containers, or Bags/Containers with Biohazard Symbols**	**Pathology Waste** **Red Bags. Red Containers, or Bags/Containers with Biohazard Symbols**	**Sharps:** **Sharps Containers; Red or marked with Biohazard Symbol**	**Chemo Waste: (trace)** **Yellow boxes or bags**	**Pharmaceutical Waste:** **Purple and White containers**	**Hazardous Pharmaceutical Waste (RCRA): Return to Pharmacy; Black Containers**
→IV bags and tubing **Empty** medication vials or containers trash/wrappers →Dressings →Chux/underpads →Empty foley bags and other drainage bags →Disposable patient items →Sanitary napkins →Gloves	→Blood and all OPIM (Other Potentially Infectious Materials) Blood tubing/ bags/ hemovacs/pleuravacs →Soaked/dripping bloody dressings →Intact glass or plastic bottles with body fluids →All disposables soaked or dripping with blood or OPIM →Contaminated waste from isolation patients →Suction canisters or liners with bloody fluid or OPIM	Pathology Waste includes all biopsy materials and all human tissues and anatomical parts that emanate from surgical, obstetrical, autopsy and laboratory procedures. Containers shall be labeled with the words "Pathology Waste" or "PATH" and the waste shall be segregated from other red bag waste. ***Labeled as "Incineration Only"***	→All sharps (except those contaminated with chemo) **Examples:** *needles, broken glass vials, broken ampoules, blades, scalpels, razors, pins, clips, etc.* →All empty syringes with attached needles, empty tubexes, empty carpujects. →Trocars, introducers, guide wires, sharps from procedures, specimen devices in endoscopy, etc.	**Trace chemo:** →All supplies used to make and administer chemo medication. *Example: tubing, empty bags/bottles/vials, syringes, gloves, pads, masks, gowns, wipes, etc.* **Return all unused Chemo to Pharmacy in original bag for disposal** ***Labeled as "Incineration Only"***	→All syringes, tubexes, carpujects with **residual (pourable)** medication. →IV bags and tubing with **residual medication.** →Partially used/ **residual** prescription or over-the-counter medication. *Example: vials, tablets, capsules, powders, eyedrops, suppositories, etc.* **Unopened/Unused or expired medications: Return to Pharmacy**	Hazardous R.C.R.A** Pharmaceuticals: Return to Pharmacy. *Example: Inhalers with residual (if empty - regular trash), unused nicotine gum or patches, epinephrine (salts not included), physostigmine, silvadene, etc.* Other RCRA items, batteries, flammables, toxic materials, caustic materials, ignitable materials. **Federal Resource Conservation and Recovery Act (RCRA)

* Always check with your State regulations for specifics.

3.0 MEDICAL WASTE ACCEPTANCE

3.1 Delivery and Reception

a) DSI picks up waste from generators off-site and delivers it to this facility

b) Waste shipments are scanned for radioactive materials upon delivery to the facility

c) Waste shipments are accompanied by manifests/shipping documents;

d) Shipments are matched to their manifest/shipping document.

   i) DSI will attempt to reconcile any significant discrepancy in a tracking document. DSI will also report any Medical Waste received without a tracking document. In either case, the discrepancy with or without a tracking document shall be reported to the Department of Environment within 15 days.

3.2 Storage Timeframes

Medical Waste will not normally be stored for extended periods. The following guidelines will be adhered to:

Maximum Storage Times for Waste:

1) Waste will be stored at the facility no longer than 90 days.

2) Putrescent waste will be refrigerated.

Housekeeping will be conducted and tracked through the Daily Cleaning Log. Daily cleaning will ensure that the facility is neat, clean and all possible operational odors are addressed and managed in a timely manner.

3.3 Security and Placarding

1) This facility must be secured to prevent access by unauthorized persons.

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

3) Storage areas must be secure to deny access to unauthorized persons, animals, insects, wind and rain.

4.0 UNAUTHORIZED WASTE PLAN

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

1) Any unauthorized waste identified upon reception will be documented on the incident log, as described below.
2) All waste will be scanned for radioactive materials upon receipt at the facility. All waste will be scanner in accordance with SOP 35 – Radiation Detection Monitoring
3) Random inspection of containers will be conducted and documented when the items are weighed/scanned into the washsmart, at least 5 containers per week will be randomly checked.
4) The facility will keep an incident log if any unauthorized waste (hazardous, etc.), improperly segregated waste (i.e.; autoclavable and incinerable waste in the same container) or improperly packaged waste (bags not tied off) is encountered.
5) The log will state the date of waste reception, generator information, and actions taken by the facility. See SOP 30 Facility Operations Logs.
6) Major or repeated violators Action Protocol
    a. Major or repeated violations are defined as more than 5 unauthorized waste incidents from one generator in a month.
7) The facility manager will contact the generator's Field Service Manager or the Area Operations Manager in order for them to contact the generator.
8) The generator will be informed of the incident and requested to submit a written follow up report on waste segregation.

9) The MDNRE will be notified of major or repeated violators within 14 business days of the incident. The notification will include the generator information, actions taken by the facility, and any written response from the generator.

5.0 WASHSMART OPERATIONS

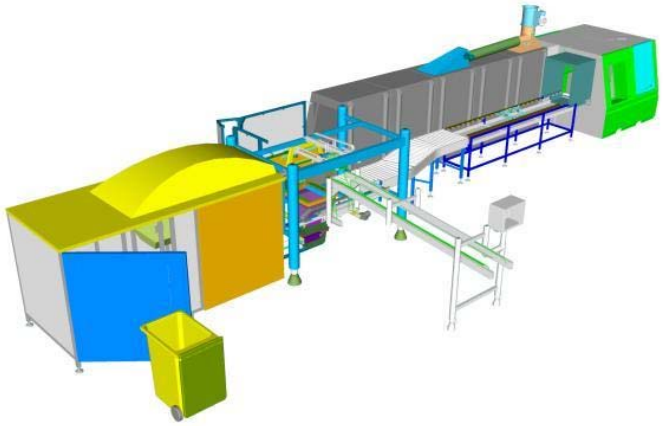

Figure 1 WashSmart System

General Description: The WashSmart System is designed to wash reusable sharps and pharmaceutical containers. Waste is picked-up from generators in re-usable sharps containers and brought to the facility for decanting. Containers filled with sharps (needles and syringes) will be put on a conveyer which will automatically feed the containers into the machine. Each container will be automatically unlocked and its contents decanted or turned upside down so the contents fall into a larger collection container. The empty containers will then move through the machine where they will be washed and dried (as described below).

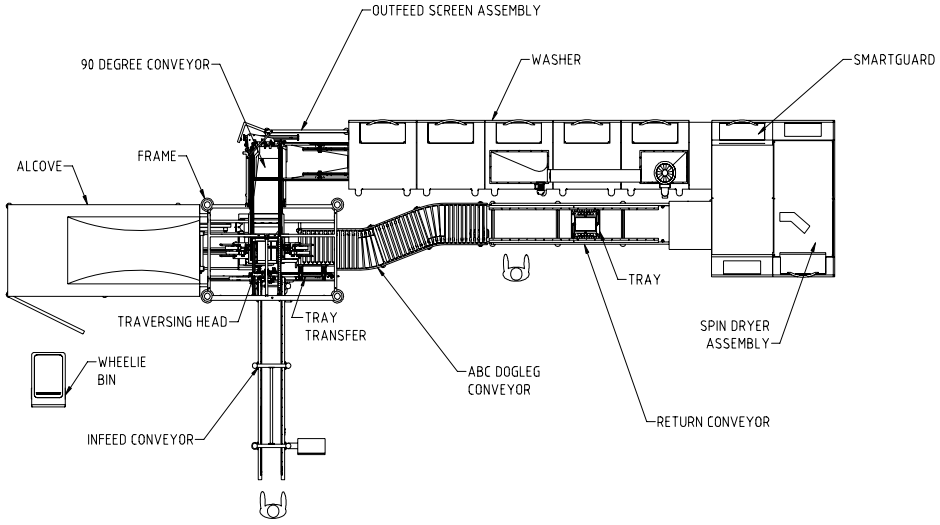

Figure 2 WashSmart Layout

1) Process Overview

i) Loading the Containers

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

ii) Opening & Emptying

a) 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.

b) The Opener secures the container and automatically unlocks and opens the container lid.

c) The container is rotated into a raised hopper and sharps contents dispensed into the Waste Bucket.

d) The empty container is then transferred along the out-feed conveyor to the Washer.

iii) Waste decanting/removal

a) Sharps bucket is emptied after each container and automatically dumped into a transport bin or Department Of Transportation (DOT) approved packaging.

i Bins are either designated for processing,

ii DOT approved packaging is used for transfer

iv) The Washing Process

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

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

ii re-wash with cold water to eliminate bulk contaminants

iii Detergent wash

(a) Eco (1st Rinse) to eliminate all detergent residue.

(b) Hot (2nd Rinse) to sanitize and thoroughly clean

v) The Smartguarding Process

a) After washing, excess water on the wash rack is removed by the first set of air knifes (which are situated on the splash guard).

b) The applicator stops the wash rack and applies Smartguard to the bin at a temperature of 55°C.

c) Excess Smartguard is removed from the wash rack, by a second set of air knifes.

vi) The Air Jet Dryer Process

a) After Smartguarding, the container is dried. Air jets cause the water droplets to be either thrown off or broken up into small droplets that dry quickly.

vii) Wash Rack Return

a) Washed & dried containers, still on the wash racks are released automatically as they are fed out onto the return conveyor.

b) An operator with clean gloves unloads bins.

Wash racks are automatically returned to the Opener for the receiving of another sharps container.

b) **ROUTINE MAINTENANCE SCHEDULE**

i) Maintenance will be conducted in accordance with the Washsmart Maintenance Manual. See appendix A

WASHSMART S2 OPERATOR CLEANING CHECKLIST

Site: _____

Operator: _____

Date: _____

Note: Ensure that correct P.P.E. is worn before working on the Washsmart

Task	P.P.E. Required
Routine Maintenance Cleaning Sanitize =	Safety boots Rubber-cloth water-proof gloves Overalls (water-proof) Safety glasses Bleach

DAILY:

- ☐ * Drain wash tanks from washer screen, after turning off both opener and washer on computer screen.
- ☐ * Sanitize opener outfeed conveyor and the two waste buckets.
- ☐ * Hose down with HOT water, opener outfeed conveyor and both waste buckets.
- ☐ * Initialize opener to empty waste buckets, then inspect and repeat process until clean.
- ☐ * Sanitize and hose right angle conveyor (bump conveyor), into flusher drawer with HOT water.
- ☐ * Open all washer doors except applicator.
- ☐ * Sanitize all washer sections.
- ☐ * Hose with HOT water all debris in flush section through opening in center.
- ☐ * Open flusher drawer.
- ☐ * After cleaning process is complete, empty and clean flusher drawer into factory waste bin.

PRE-WASH SECTION:

- ☐ * Hose debris into top filter tray.
- ☐ * Empty and clean filter into flusher drawer.
- ☐ * Remove and clean, three of tank filters into flusher draw.
- ☐ * Check and clear bottom of tank of any debris.
- ☐ * Check floats are free from debris

DRIVE SECTION:

- ☐ * Sanitize and clear debris using tongs or similar apparatus.
- ☐ * Check and clear two drainage filters.

WASH SECTION:

- ☐ * Hose debris into top filter tray.
- ☐ * Empty and clean filter into flusher drawer.
- ☐ * Remove and clean, three of tank filters into flusher draw.
- ☐ * Check and clear bottom of tank of any debris.
- ☐ * Check floats are free from debris

RINSE SECTION:

- ☐ * Hose debris into top filter.
- ☐ * Empty and clean filter into flusher drawer.
- ☐ * Check and clean 1 filter in tank.
- ☐ * Check and clear bottom of tank of debris.
- ☐ * Check floats are free from debris

APPLICATOR SECTION:

- ☐ * DO NOT use any water within this section, this would result in altering the concentration of the Smartguard.
- ☐ * Check and clean two top tank filter trays.

CONTAINER REMOVAL CONVEYOR:

- ☐ * Clean and sanitize

SPINNER SECTION:

- ☐ * Check on and around turntable area and ensure it's clear from debris.
- ☐ * Sanitize spinner area.

WEEKLY:

OPENER:

- ☐ * Check that barcode scanner is logging barcodes
- ☐ * Wipe front lense of safety scanner with clean lint-free cloth
- ☐ * Check condition of suction cups and clean using water and detergent
- ☐ * Inspect condition of R.H.S. & L.H.S. side latch release tags

SPINNER SECTION:

- ☐ * Before cleaning ensure emergency stops are pressed in, turn the control key to the off position and remove key.
- ☐ * Remove end panel from spinner and using a pan and broom remove all debris from base of spinner section.

GENERAL:

- ☐ * Inspect opener section and clean any dust or grime from all areas.
- ☐ * Clean outside of entire machine where required to maintain the highest standard of cleanliness and good appearance.

WASHSMART S2 OPERATOR MAINTENANCE CHECKLIST

Site: _____

Operator: _____

Date: _____

Note: Ensure that correct P.P.E. is worn before working on the Washsmart

Task	P.P.E. Required
Routine Maintenance Cleaning	Safety boots Rubber-cloth water-proof gloves Overalls (water-proof) Safety glasses

Every 4 weeks

☐ Grease Nipples - On Bearings using heavy duty waterproof grease/Lithium based grease # 2

☐ 2 off – At the end of the infeed conveyor at the base.

☐ 2off – On the lower RHS of the opener head tipper.

☐ 4 off – 1 of at the base of each liner and key assemblies.

☐ 2 off – On the base of the tray transfer assembly.

☐ 2 off – On the base of the waste bucket assembly.

☐ 2off - On the pivot shaft of the second waste bucket assembly.

☐ 4 off – At the end of the opener outfeed conveyor, at the bump conveyor.

☐ 2 off – On the washer drive conveyor, located behind the panel below the third washer door.

IMPORTANT: **DO NOT** GREASE ANY CYLINDER SHAFTS

Clean each of the following shafts & rails & then grease each of these shafts & rails:-

☐ 2 off – Pick & Place guide shafts.

☐ 1 off – Tray transfer guide rail.

☐ 4 off – Key and liner inserter assembly guide rails.

☐ 2 off – Waste bucket guide shafts.

☐ 2 off – Bump conveyor guide shafts.

☐ 2 off – Spinner steady cylinder guide shafts.

6.0 Medical Waste Processing

1. General Information. Medical Waste will be treated on-site in an autoclaves.

   a) This facility operates Autoclaves as describe in Appendix C – Autoclave Specifications.

   b) The autoclave will be operated 24 hours a day, seven (7) days a week.

   c) An estimated 20,000 tons (40,000,000 lbs.) of waste will be processed by the facility annually.

   d) The **biological indicator** *Bacillus stearothermophilus*, or other indicator of adequate sterilization as approved by the department, shall be placed at the center of a load processed under standard operating conditions at least weekly to confirm the attainment of adequate sterilization conditions. The biological indicator test will be conducted in accordance with the Appendix E - Autoclave Test Protocol.

   e) Records pertaining to Special Medical Waste treatment and calibration shall be maintained as part of the facility's files and records for a period of five years

   f) Only trained, approved personnel may operate the autoclave. The procedure and information related for autoclaving waste is provided in treatment using procedures described in Appendix D- Autoclave Operations and Maintenance Manual and Appendix E- Autoclave Test Protocol.

   g) The calibration and maintenance of the autoclave will be conducted annually according to manufactures recommended maintenance schedule.

h) In accordance with allowable storage time, the Special Medical Waste will be treated using procedures described in the Autoclave Operations and Maintenance Manual (APPENDIX D) and the Autoclave Test Protocol (APPENDIX E).

2. Process Overview.

a) Waste will be loaded into waste treatment carts.

b) The carts will be moved into the autoclave.

c) The autoclave will be closed, and sealed, then brought appropriately to pressure and temperature.

d) The waste will be treated for the appropriate time.

e) The pressure from the autoclave will be released.

f) The waste will then be removed from the autoclave then placed in the compactor.

g) The treated waste will then be designated as Solid Waste and will be placed into a compactor for disposal the following approved landfill:

(1) Landfill - TBD I'm currently working on an agreement with Republic Services at their Saulk Trail Landfill in Canton, MI..

APPEDIX D

AUTOCLAVE SPECIFICATIONS

1.1.1 AUTOCLAVE DIMENSIONS AND CAPACITY

Model:	BTT6X30
Size:	6' dia x 30' long
Number of bins:	6/load
Cycle time:	45 minutes
Bin Dimensions:	Approx 58" W X 58" L X 45.5" H
	4.83' W X 4.83'L X 3.8' H
	88.65 cu.ft

Rated Capacity Cycle Time = 45 to 50 minutes (load to load)

@ 4.0 # / cuft = 355 # / bin X 5 bins = 1,775 # /cycle (2,130 #/hr - 2,367 #/hr)
@ 5.5 # / cuft = 488 # / bin X 5 bins = 2,240 # /cycle (2,688 #/hr - 2,987 #/hr)

1.1.2 AUTOCLAVE VESSEL SPECIFICATIONS

Working Pressure:	75 psig
Safety Relief Set Point:	55 psig
Opening Assembly:	Single door/quick opening door/safety pin interlock

1.1.3 VACUUM SYSTEM.

Vacuum Pump: Vacuum: 22-28" Hg.
High Efficiency Steam Ejector.

Vacuum Capability: 22" Hg, 4 to 5 minutes maximum – pre-vacuum.

Pre-vacuum: The pre-vacuum process will evacuate the autoclave 22" to 28" Hg.

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

1.1.4 STEAM CONDENSER

Independent steam condenser manufactured of pressure-grade steel. The condenser is designed for quick and efficient steam purge from the autoclave vessel. Process steam is condensed externally to the autoclave vessel.

1.1.5 DOOR OPERATION, SEALING AND LOCKING MECHANISM

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

1.1.6 MATERIAL HANDLING – LIFT TABLE

A metal shuttle cart will be installed to move the waste on a train system into and out of the autoclave.

APPEDIX E

AUTOCLAVE OPERATIONS AND MAINTENANCE MANUAL

TABLE OF CONTENTS

I. TREATMENT METHOD

1 Steam Autoclave Summary.

DSI will treat medical waste through BTT steam sterilization autoclave so that the waste can be safely deposited in permitted solid waste landfills. The medical/medical waste is subjected to pressurized saturated steam that delivers the thermal treatment required for effective decontamination rendering the waste non-infectious and safe for disposal at a sanitary landfill.

The autoclave temperature and pressure are continuously monitored and recorded during the entire length of each autoclave cycle for assuring that proper operating temperature has been achieved. In addition, biological indicators are utilized periodically for quality control.

The system process control records and generates informative data illustrating the environment (time, temp. and pressure) of every load processed. Bacillus stearothermophilus spores are placed in the center of a waste load once per week. A quality control log for recording the biological indicator results is maintained within the facility. The temperature/pressure data charts and the quality control logs provide the environmental regulatory agency with essential information that establishes reasonable assurance of effective medical/medical waste treatment.

1.1 Biomedical Waste Treatment Procedure.

The shift supervisor shall review daily autoclave production records for accuracy and integrity. The records shall be maintained at the facility.

a. Place a high temperature autoclave bin liner in empty autoclave bin.
b. Load biomedical waste into autoclave bin.

WARNING: FILL NO HIGHER THAN THREE (3) INCHES BELOW THE RIM.
DO NOT COMPLETELY FILL OR OVERFILL BINS!

c. Transfer loaded waste bins into the autoclave unit.
d. Close autoclave door and activate door lock hydraulic system until autoclave door is fully locked. Engage mechanical safety arm.
e. Start autoclave process cycle (Press Green Button on Autoclave Control Panel).
f. After completion of process cycle, verify that steam pressure has been vented.

WARNING: CONFIRM NO PRESSURE IN AUTOCLAVE
Visually Check Digital Readout (should be less than 2psig)
Visually Check the Analog Pressure Gauge (should be 0 psig)

g. Disengage mechanical safety arm and confirm no pressure release on ball float.
h. Activate door unlock hydraulic system until autoclave is fully unlocked.
i. Open autoclave door to its fully open position & locked position.

WARNING: HOT AIR IN AUTOCLAVE CHAMBER.
DO NOT GO INSIDE AUTOCLAVE CHAMBER.
DO NOT STAND ON LIFT TABLE LOOKING INTO AUTOCLAVE.

USE BIN RETRIEVING ROD TO REMOVE AUTOCLAVE BINS.

j. Activate lift table and transfer the waste bin to the compactor dumper.

1.2 Emergency Shutdown Procedure.

The autoclave operators have the capability to command an emergency shutdown of the waste treatment process cycle at any time. If a system problem develops, then the operator can immediately shut down the cycle by activating the cycle stop on the control panel or turning power off. Waste that has experienced an Emergency Shutdown/Abort must be re-subjected to another waste treatment cycle.

If an autoclave operator executes an emergency shutdown, the operator must notify the supervisor. The supervisor shall conduct immediate inspection and determine cause and corrective action. The supervisor shall require all biomedical waste that experienced an Emergency Shutdown be re-subjected to a complete autoclave process cycle.

1.3 Process Cycle Description.

THE FOLLOWING OPERATIONAL PARAMETERS HAVE BEEN ESTABLISHED FOR THE BONDTECH AUTOCLAVE IN BALTIMORE. THESE PARAMETERS WILL BE MAINTAINED AND CANNOT BE CHANGED WITHOUT PERMISSION OF THE COMPLIANCE MANAGER.

The bondtech autoclave operates with 3 pre-vacs. The settings for these to pull a vacuum with a set point of -7 psi followed by a pre-heat of 275 degrees for 3 minutes.

The heat segment settings are:
Temp set point: 275 degrees
Time: 10 minutes

The cycle then is followed by a vent segment (takes it back to ambient)
The next segment is the post vacuum and these settings are:
Pressure setting: -7 psi
Time: 2 minutes. This time was determined to be enough to evacuate all of the steam and condensate from the vessel.

The last segment is the vent for 1 minute which takes the pressure back to ambient and the cycle ends.

Total processing time: Estimated to be 22 minutes.

2.0 Quality Assurance Summary.

Each autoclave unit is evaluated for effectiveness with spores of bacillus stearothermophilus, or equivalent. A bacillus stearothermophilus ampoule (biological indicator) shall be placed into the center of one waste bin loaded into the Bondtech autoclave. The results of the biological test shall be recorded and maintained on written logs at the facility.

2.1 Biological Monitoring Procedure.

a. Mark the "Challenge" biological ampoule with date, time and autoclave unit number.
b. Place "Challenge" biological ampoule in the approximate center of a fully loaded waste bin.
c. Process waste load in accordance with Section 3.0.
d. Retrieve the "Challenge" biological ampoule.
e. Place "Challenge" biological ampoule into the incubator and record date and time onto Quality Control Log.
f. Mark a virgin "Control" biological ampoule with the letter "C" and the date and time.
g. Place "Control" biological ampoule into the incubator.

- Only one "Control" ampoule is required for each batch order number of the ampules.
- Incubator shall be performed in accordance with the manufacturer's instructions.

h. After incubation period, retrieve the "Challenged" ampoule and the "Control" ampoule and examine liquid color change as follows:

NO COLOR CHANGE = Negative Growth (Pass - Satisfactory Treatment)
COLOR CHANGE = Positive Growth (Fail - Unsatisfactory Treatment)
* The "Challenged" ampoule should exhibit *NO COLOR CHANGE*.
* The "Control" ampoule should exhibit *COLOR CHANGE*.

I. Record results onto autoclave Quality Control Log.
See SOP 30 Facility Waste Log

2.3 Biological Ampoule Description.

An ampoule containing bacillus stearothermophilus, or equivalent, spores is placed in the center of a waste load to monitor autoclave performance for sufficient temperature and pressure for sufficient time to kill the spores. Each autoclave unit is evaluated for effectiveness with the biological ampoule on a monthly basis.

I. Objective

Conduct a challenge test per the requirements of the Maryland Department of the Environment as it pertains to autoclaving of Regulated Medical Waste. Biological Indicators (BI) – *Geobacillus stearothermophilus* shall be used to assess the process by placing indicators in the waste to demonstrate a ≥10e4 log reduction of bacterial spores.

II. Testing oversight

A. Onsite Test Manager: Plant manager or designee
B. Testing Lab: On site incubation

III. Protocol

A. Raven Labs Biological Indicators (BI) shall be placed into bags of waste located at the bottom 1/4 of each cart. BIs (Raven Prospore 2 ampoules containing 10e5 concentrations of *G. stearothermophilus*) shall first be inserted into a Teflon tube (see description below). Each tube shall be numbered and a solid Teflon plug shall be inserted into the top of each tube to eliminate steam travel down the tube.

B. Tubes shall be place into each bin. Each bin shall contain a minimum of 3 sampling tubes/locations. Samples/tubes shall be placed in random locations for each test run as per the diagram below (as an example):

Bin 1	Bin 2	Bin 3	Bin 4	Bin 5	Bin 6
X	X	X	X	X	X
X	X	X	X X X	X	X
X	……X	X	……X	X	…… X

Autoclave door

Note: Use care in inserting Teflon tubes. A rigid pipe may be used to create a path for the Teflon tube to be inserted. A jig may be designed that holds 3 tubes in place while a bin is being filled with sharps when sharps containers are being decanted at the Washsmart.

Exercise case in handing any device used as a guide for the Teflon pipes and decontaminate using available disinfectants after use.

C. Teflon tube construction/design - Teflon tube - 3 feet in length, 7/8 inch inside diameter, and 1 inch outside diameter, with a Teflon plug at the bottom of the tube containing a ¼ inch hole drilled through the solid piece to allow for liquid and/or steam to pass through. The bottom of each Teflon tube should have 5-6 sets of holes drilled approximately 1 ¾, 2 ¾, and 3 ¾, 4 ¾, 5 ¾, and 6 ¾ inches (a minimum of 5 holes at each position) from the end to allow for steam penetration. A solid numbered Teflon plug should be inserted in the top of each tube.

IV. Data collection

A. Data should also be collected regarding waste load composition and weight for each cycle when feasible

V. Analysis

A. Upon recovery, Prospore 2 ampoules shall be incubated for 24 hours at 55-60^{o}C and results recorded on the format at the end of this document.

3.0 Training/Routine Maintenance Checks

3.1 Operator Training.

Prior to operating the biomedical waste treatment autoclaves, the employee must read and understand this Standard Operating Procedure. The facility manager will provide a plant tour and demonstrate on the job training.

The executed Facility Training Certification will be documented into the personnel files.

3.2 Routine Maintenance Checks.

The autoclave treatment system is visually inspected on a daily basis for steam leaks, water leaks, and steam trap blockage. Significant steam and water leaks that inhibit effective operation or exposure personnel to unsafe conditions will require immediate shutdown of the problem autoclave unit. Similar discrepancies noted with the boiler and/or steam supply piping will require shutdown of the boiler and waste treatment operation. The noted discrepancy will be immediately rectified. The autoclave and boiler shall be operated and maintained in accordance with the manufacturers O&M manuals.

3.3 Mercury Control System.

The autoclave will be equipped with the CARBTROL G-3B1000 Air Purification System to remove any VOCs that will be discharged from the autoclave. System design is as follows:

A (18” x 24” x 72”) welded stainless steel hood will be positioned 12” over the door opening of the Autoclave and connected by an 10” round metal pipe to a Carbtrol G-3B1000 Air Purification System. G-3B1000 system is equipped with a 3HP TEFC Blower, 1 phase 115V, with Manual Motor Starter. The Carbtrol System will be fitted with two (2) activated carbon canisters. The two (2) G-3P canisters in the system are designed for flows to 500 CFM each and contain 140 pounds of virgin high capacity vapor phase activated carbon. Saturation Indicator for placement on the blower discharge. Indicator changes color indicating the carbon is saturated and need to replace the canisters on the system.

The design of the system is as follows:

1. 2 minutes prior to the autoclave door opening after a treatment cycle, the exhaust hood blower will be activated to draw any potential air emissions.
2. As the door is opened the air is exhausted into the hood.
3. The air is vented through the 10” metal pipe fitted at the top of the hood to allow for the draft flow of air from the hood to the carbon system via a blower.
4. The air then is blown into the carbon filter system. This is a series of two (2) carbon drums.
5. The drums will be fitted with a saturation indicator for ease of use. Once the indicator shows full saturation at the saturation set point, the drums will be replaced.
6. All used drums will be properly disposed.

The Carbitrol System will be inspected daily through the following check list:

Inspection Item	Status	Comments/Corrections
Hood systems working properly		
Ducts in tact		
Carbon system operational		
Carbon saturation meter working		
Carbon saturation level checked		

7.0 Disposal

a) All medical waste will be managed as medical waste and is shipped to a permitted treatment facility for final treatment and disposal.

b) Once the waste is properly treated on-site, it will be placed in a compactor.

c) Once the compactor is full the waste (treated) will be sent to an approved, permitted landfill for final disposal.

d) The following are facility is to be used to accept our medical waste:

i) TBD

You will need to identify this. TBD I'm currently working on an agreement with Republic Services at their Saulk Trail Landfill in Canton, MI

8.0 Transfer of Waste

Waste will be properly packaged and transported to an approved Offsite Treatment Facility.

9.0 CLOSURE PLAN

Upon closure of the facility, all equipment, facilities, and non-disposable items used in the operation of the treatment process will be decontaminated either by steam sterilization or by disinfection with a commercial quaternary ammonium salt disinfectant, mixed and used per the manufacturer's directions.

The following closure plan will be implements once closure has been determined:

i) In the event this facility is to be closed the facility must be thoroughly cleaned and disinfected and all medical waste must be disposed in accordance with all applicable regulations.

ii) Notification of the intent to close the facility will be given to the Department of Natural Resources and Environment (DNRE) prior to the anticipated date of closing.

iii) A closure timeline will be developed to include:

   (1) Date of last accepted waste load.

   (2) Anticipated date of final shipment.

   (3) Milestones, as appropriate.

iv) A sign stating "SITE CLOSURE" and "FURTHER WASTE LOADS ARE PROHIBITED" will be posted upon acceptance of last waste load.

v) Site clean-up will take place within 6-days of closure, unless otherwise approved by the DNRE.

vi) The following are the steps to be taken during site closure and clean-up:

(1) All MEDICAL WASTE shall be loaded onto vehicles and transported to a permitted MEDICAL WASTE Offsite Treatment Facility by a properly permitted transporter.

(2) All supplies for packaging MEDICAL WASTE shall be removed and returned to the supplier or properly disposed.

(3) All surfaces of any equipment used to handle MEDICAL WASTE packages shall be thoroughly cleaned and disinfected. All wastewater from these cleaning operations must be discarded into the sanitary sewer and not onto the ground or into storm sewers.

(4) Remove all company names from the facility and all biohazard and MEDICAL WASTE warning signs and labels.

(5) All appropriate paperwork shall be transferred to the Daniels Sharpsmart, Inc corporate office, and kept for three years.

(6) Remove all other Daniels Sharpsmart assets from the property. Turn over all keys to the landlord representative and obtain receipt for property turned in.

(7) The DNRE shall inspect all regulated Medical Waste management facilities that have been closed to determine if the closing is complete and adequate. It shall notify the owner of a closed facility, in writing, if the closure is satisfactory, and shall order necessary construction or such other steps as may be necessary to bring unsatisfactory sites into compliance with this chapter. Notification by the DNRE that the closure is satisfactory does not relieve the operator of responsibility for corrective action to prevent or abate problems caused by the facility.

10.0 CONTINGENCY PLAN

Additional general guidelines for cleaning up medical spills are provided in **the Westland Emergency Contingency Plan (*Appendix F*)** and the **Bloodborne Pathogen Exposure Control Plan (Appendix G).**

10.1 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.

10.2 Contamination of Equipment and 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 (e.g., biological, radioactive, and chemical).

• Report details and request assistance by contacting COMPLIANCE if the incident is during normal working hours. If the incident occurs after hours contact the Site Operations Manager.

• 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 pickup any sharp items, even if gloves are worn.

• Decontaminate the equipment and area under a supervisor's direction using appropriate methods.

• Stand by to provide emergency information and assistance to Emergency Response Personnel, if required.

10.3 Release to the Environment (air, water, soil)

• Stop the release, if safe to do so.

• Follow procedures described above for contamination of equipment and facility.

• Make immediate notifications. Any information of a release or discharge of Medical Waste from or of a fire or explosion at a Medical Waste facility which could threaten the environment or human health outside the facility. The description of the occurrence and its cause shall 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.

10.4 Equipment Failure

1) In the unlikely event that Medical Waste must be transported off site, all Medical Waste and sharps will be moved in compliant containers for processing.
2) Waste would be taken to the following back-up location:
   a) Stericycle Inc. (CID 134419)
   b) 1301 E Alexis Rd
   c) Toledo, OH 43612

3) DSI will not store biohazardous or sharps waste at the facility for not more than 20 days without obtaining prior written approval of the MDNRE.

101.5 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 of any emergency occurrence.

Implement Emergency Notification Plan.

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 Chandlery St.
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.

Employee safety is the next priority: The Emergency Response Coordinator will determine if implementation of evacuation is appropriate. The employee parking area will be used to rally employees for accountability and availability.

APPENDIX F Westland Emergency Contingency Plan

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 Supervisor approval. Notify COMPLIANCE immediately of any spills that have the potential for serious health or safety implications.

1. Determine the nature and the extent of the spill—what has been spilled (i.e., the chemical or biological agent), its concentration, quantity, and location.

2. Evacuate the area immediately (if necessary to prevent exposure of additional persons to a particularly toxic or virulent agent).

3. Provide immediate medical treatment to those exposed (if warranted by the nature of the exposure).

3. 4Secure and post the spill area to prevent additional exposures and spread of the spill.
    a. Storm drains will be covered with either temporary covers of by pillos spill dikes to avoid discharging to the drain.

5. Put on appropriate personal protective equipment (PPE).
    a. Always: glasses, gloves, lab coat or apron, shoe coverings.
    b. As appropriate (depending on the nature of the spill): face shield or goggles, respirator, boots.

6. Contain the spill (e.g., by dyking or ringing with absorbent material).

7. Decontaminate the spilled material if warranted (i.e., it is often prudent to decontaminate the spilled material before it is picked up). Disinfect using 10% bleach solution or another approved disinfectant (see section 10.6) for a thirty-minute contact time.

8. Pick up the spilled material:

a. Solids:

1. Pick up by mechanical means (e.g., pan and brush, forceps).

2. Discard as medical, hazardous, or radioactive waste as appropriate.

b. Liquids:

1. Absorb the spill with absorbent material as appropriate (e.g., paper towels, vermiculite).

2. Discard as medical, hazardous, or radioactive waste as appropriate.

c. Broken glass and other sharps:

1. Pick up by mechanical means (e.g., forceps, pan and brush), never by hand.

2. Dispose as sharps.

9. Decontaminate the area using an appropriate disinfectant (see Section 10.6).

10. Rinse/clean the area (if necessary) and absorb and collect waste materials.

11. Dispose of collected material and cleanup materials as medical, hazardous, or radioactive waste as appropriate.

12. Decontaminate reusable items (such as dust pans, brushes, forceps).

13. Remove personal protective equipment (PPE).

a. Discard disposable items as medical, hazardous, or radioactive waste as appropriate.

b. Decontaminate reusable items (such as heavy rubber gloves, boots, aprons, gowns) before cleaning or laundering.

14. Wash all exposed skin thoroughly.

15. Perform medical treatment and follow up as appropriate for the particular type of material.

APPENDIX G

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

11.0 TRAINING PLAN

Personnel handling Medical Waste must be properly trained. Through careful and thorough management of the training regimen, each employee is given the tools to assure his/her success. Specific training pertaining to Medical Waste handling operations will cover:

1) Facility personnel shall successfully complete a program of ***on-the-job training*** that teaches them to perform their duties in a way that ensures the facility's compliance. It is vital to the ultimate success of the program that each individual understands the importance of each and every function within the facility. Everyone is encouraged to observe and cross train in other areas giving them expanded expertise and skills. Through a series of hands on supervised sessions, the employee is taught the necessary skills to insure success. Once initial orientation training is finished the employee, working side by side with a mentor, must demonstrate a thorough understanding of the tasks and show proficiency in his work.

2) The Daniels Sharpsmart, Inc. Training Regimen incorporates both of ***Bloodborne Pathogen Exposure Control and Hazard Communication training***.

3) Employees engage in ***Washsmart use and maintenance training***. This includes putting all the theoretical training provided to practical use. Over a two-day period the machine operators and maintenance personnel are observed and assisted in an attempt to familiarize themselves with the machine. The conclusion of the practical session is an interactive computer aptitude test that evaluates the knowledge gained over the training modules.

4) Training is required for the ***operation of the Autoclave***. Initial training for operators and trainers is provided as part of installation package. Ongoing, annual, training and additional initial training is provided as part of maintenance program. Once training is completed, the trainee's information is updated in the autoclave database and a certificate of training will be provided. The following sections of this manual provide basic operating instructions.

5) The training will include ***requirements of applicable permits***.

6) The training program shall ensure that facility personnel are able to respond effectively to ***emergencies*** by familiarizing them with emergency procedures, emergency equipment, and emergency systems, including, where applicable:
   a) procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment;
   b) key parameters for automatic waste feed cut-off systems;
   c) communications or alarm systems;
   d) response to fires or explosions; and
   e) shutdown of operations.

7) Facility personnel shall successfully complete the training within six months after the date of their employment or assignment to a facility, or to a new position at a facility. Employees hired after the effective date of these regulations shall not work in unsupervised positions until they have completed the training requirements.

8) Facility personnel shall take part in an annual review of the initial training.

9) The following documents and records shall be maintained at the facility:

   a) Records that document that the training or job experience has been given to, and completed by, facility personnel.

10) Training records on current personnel shall be kept until closure of the facility; training records on former employees shall be kept for at least five years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

12.0 MEDICAL WASTE MANAGEMENT PLAN

MEDICAL WASTE TRANSFER FACILITY

MEDICAL WASTE MANAGEMENT PLAN

DANIELS SHARPSMART, INC.
Westland, MI
Telephone: 734-729-7044
July 2010

A. Individual responsible for the management of Medical Waste:
1 Primary Contact Person
Darren Whitman phone 734-729-7044; 734-306-8153 (cell)

2 Backup Contacts
Evan August phone 423-432-1099

B. Types of Medical Waste Handled:

- ✓ 1. Cultures and stock of infectious agents and associated biologicals, including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture dishes, and related devices.
- ✓ 2. Liquid human and animal waste including blood, blood products, and body fluids but not including urine or materials stained with blood or body fluids.
- ✓ 3. "Pathological waste" means human organ tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery, autopsy, or other medical procedure.
- ✓ 4. "Sharps" means needles, syringes, scalpels, and intravenous tubing with needles attached.
- ✓ 5. Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals.

C. Medical waste handled, the segregation, packaging, labeling, and collection procedures used:
All waste brought to this facility is properly packaged and labeled prior to reception at this facility. Packaging is completed at the generation site.

1. SHARPS:
   Sharps are placed into an appropriately labeled sharps container before being stored and/or removed from the generator.

   Sharps will be stored at the facility no longer than 30 days.
   Brought into the facility in rigid, puncture-resistant containers that are appropriately labeled and transported to the DSI transfer facility in a manner that retains the integrity of the container.
   Reusable sharps containers will be decanted (on-site), then cleaned, and put back into use in accordance with FDA requirements.
   Decanted waste will be properly placed in rigid, puncture-resistant containers that are appropriately labeled and transported to the off-site treatment facility in a manner that retains the integrity of the container.
2. BLOOD AND BODY FLUIDS:

Blood and Body Fluids brought to the facility are already properly packaged and will be transferred in accordance with the regulation.

3. CLUTURES AND STOCKS:
   Brought to this facility in closed, puncture resistant containers and transferred by our company or subcontract company for autoclaving or incineration prior to disposal in a sanitary landfill.
4. PATHOLOGICAL WASTE:
   Brought to this facility in closed, puncture-resistant, properly labeled containers,
   Transferred by our medical waste disposal company for off-site treatment by incineration.
5. CONTAMINATED ANIMAL WASTE:
   Brought to this facility in appropriately labeled containers and removed by our medical waste disposal company. The waste is treated via incineration prior to disposal in a sanitary landfill.

D. Describe the use and methods of on-site or off-site storage:

Stored in appropriate containers (biohazard bin, box) in a designated storage area until transferred by our medical waste company to an off-site treatment facility.

E. Describe the use and methods of off-site decontamination/treatment:

Medical waste transferred at this facility is decontaminated/treated off-site by autoclaving or other method specified below by a medical waste treatment facility prior to disposal in a sanitary landfill
The waste is autoclaved at:
Stericycle Inc. 1301 East Alexis Road Toledo Ohio 43612 419-729-8006, CID: 134419

F. Describe the use of off-site incineration:

Healthcare Environmental Service, INC. 1420 40th Street NW Fargo, ND 58102 Phone Number 701-282-7373 Permit Number (incineration) ITF 0203

G. Indicate the corporate or other legally recognized business name and address of any solid waste hauler who transports medical waste for this producing facility:

Stericycle Inc 1301 East Alexis Road Toledo Ohio 43612 419-729-8006 CID: 134419

H. Sanitary landfills for waste disposal once waste has been treated at the off-site treatment facility:
   Allied Waste Vienna Junction Industrial Park Sanitary Landfill Michigan License # 9173

I. Measures to minimize exposure of the facility's employees to infectious agents throughout the process of handling and disposing of the medical waste, including, where applicable, the use of protocols, procedures and training, personal protective devices and clothing, physical containment or isolation devices or systems, and prevention or control of aerosols:

Bloodborne Pathogens training is required for each employee with potential exposure initially upon hire, and refresher training is provided on an annual basis. These records are maintained at the facility. Training is provided upon hire regarding proper handling of medical waste, and is performed before the employee assumes duties that involve handling of medical waste as required by R 325.1547 of the MWRA. All employees receive refresher training when a change in the medical waste management plan directly affects the employee's duties. Records are maintained at the facility which includes the employee's name, job classification, and dates of training as required. Training records are maintained for a minimum of 3 years.
Employees are provided gloves (leather and/or rubber); eye protection and dust mask (if appropriate) depending on the specific job function.

J. The DSI Transfer facility shall comply with its medical waste management plan.
K. Upon request, DSI shall make its medical waste management plan available to the department.

L. Upon receipt of 24 hours advance notice, DSI shall make its medical waste plan available to an employee of the facility for inspection on the premises or provide a copy of the medical waste management plan to the employee.

Policy Title:	Radiation Detection Monitoring
Policy Number:	35
Date Issued:	July 2010
Version:	July 2010
Issuer Name:	Andrea Arredondo
Next Review Date:	July 2011
Applying to the following functional areas:	All processing plants; transfer facilities as required.
Purpose:	To describe the radiation monitoring system and use.

a) Waste brought into and treated at the facility will be monitored for radioactivity.

b) Daniels Sharpsmart, Inc. will purchase and utilize a Ludlum wall mount monitoring system for the processing of waste.

c) Prior to use the detection equipment will be tested with a known radiation source and action will be taken as necessary to ensure the alarm is operating when a radioactive source 3x background is reached.

i) All containers will be checked for radioactive sources at 3x background.

d) The set-up, operation, maintenance and calibration of the radiation detection units shall be conducted in accordance with the manufacturer's suggestions.

i) Compliance will be responsible to schedule all annual calibration.

ii) Plant must notify Compliance immediately of any non-operable equipment, or equipment in need of maintenance or repair.

e) Personnel will be trained on the use and requirements of the monitoring equipment prior to commencement of operations.

f) An area away from workers shall be maintained for the isolation of medical waste that has caused the detection equipment to alarm.

g) Any container of medical waste that causes the detection equipment to alarm will be given special handling considerations. Conditions are as follows:

i) If the waste reads **greater than** 3x background, **but less than** 1,000 micro R per hour or equivalent,

(1) The facility will set aside the waste in an isolation area for 48-hours then re-scan for radioactivity.

(2) If the re-scan indicates the waste has decayed to a level of 3x or less background then the waste can be treated.

(3) If the re-scan is still above 3x background Compliance shall be notified and further directions shall be provided, including the possibility of holding the waste for further decay.

ii) If the waste is **greater than** 1,000 micro R per hour or equivalent, the container of waste shall immediately be set aside in the isolation area.

(1) Immediate contact will be made with **ALL** of the following organizations:

(a) The generator

(b) COMPLIANCE

(2) Further directions shall be provided from the above named organizations, including having the generator make arrangements to have the radioactive materials returned to their site.

h) All containers causing the detection meter to alarm will be documented on SOP 30 Plant Operations Logs – Unauthorized Waste Log