MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION

September 21, 2012

PERMIT TO INSTALL
144-12

ISSUED TO
TreatMed, Inc.

LOCATED AT
41200 Coca-Cola Drive
Van Buren, Michigan

IN THE COUNTY OF
Wayne

STATE REGISTRATION NUMBER
P0379

The Air Quality Division has approved this Permit to Install, pursuant to the delegation of authority from the Michigan Department of Environmental Quality. 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: **September 21, 2012**	
DATE PERMIT TO INSTALL APPROVED: **September 21, 2012**	SIGNATURE:
DATE PERMIT VOIDED:	SIGNATURE:
DATE PERMIT REVOKED:	SIGNATURE:

PERMIT TO INSTALL

Table of Contents

Section **Page**

Common Abbreviations / Acronyms

Common Acronyms		Pollutant / Measurement Abbreviations	
AQD	Air Quality Division	BTU	British Thermal Unit
BACT	Best Available Control Technology	°C	Degrees Celsius
CAA	Clean Air Act	CO	Carbon Monoxide
CEM	Continuous Emission Monitoring	dscf	Dry standard cubic foot
CFR	Code of Federal Regulations	dscm	Dry standard cubic meter
CO_2e	Carbon Dioxide Equivalent	°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
GHGs	Greenhouse Gases	kW	Kilowatt
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
MDEQ	Michigan Department of Environmental Quality (Department)	PM	Particulate Matter
MSDS	Material Safety Data Sheet	PM10	PM less than 10 microns diameter
NESHAP	National Emission Standard for Hazardous Air Pollutants	PM2.5	PM less than 2.5 microns diameter
NSPS	New Source Performance Standards	pph	Pounds per hour
NSR	New Source Review	ppm	Parts per million
PS	Performance Specification	ppmv	Parts per million by volume
PSD	Prevention of Significant Deterioration	ppmw	Parts per million by weight
PTE	Permanent Total Enclosure	psia	Pounds per square inch absolute
PTI	Permit to Install	psig	Pounds per square inch gauge
RACT	Reasonably Available Control Technology	scf	Standard cubic feet
ROP	Renewable Operating Permit	sec	Seconds
SC	Special Condition	SO_2	Sulfur Dioxide
SCR	Selective Catalytic Reduction	THC	Total Hydrocarbons
SRN	State Registration Number	tpy	Tons per year
TAC	Toxic Air Contaminant	µg	Microgram
TEQ	Toxicity Equivalence Quotient	VOC	Volatile Organic Compound
VE	Visible Emissions	yr	Year

* 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 Environmental Quality, P.O. Box 30260, Lansing, Michigan 48909-7760, 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 Environmental Quality. **(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)	Flexible Group ID
EU-AUTOCLAVE1	A T2000 Sterilizer: 660 gallon capacity, double-walled, water-cooled steam autoclave for the treatment of regulated medical waste. Condensate and air are evacuated from the chamber at the completion of the cooling cycle, then the blowdown/condensate tank discharges to the sanitary sewer. Steam is generated by a 2.0 MMBtu/hr (50 hp) natural gas fired boiler.	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: EU-AUTOCLAVE1

DESCRIPTION: A T2000 Sterilizer: 660 gallon capacity, double-walled, water-cooled steam autoclave for the treatment of regulated medical waste. Condensate and air are evacuated from the chamber at the completion of the cooling cycle, then the blowdown/condensate tank discharges to the sanitary sewer. Steam is generated by a 2.0 MMBtu/hr (50 hp) natural gas fired boiler.

Flexible Group ID: N/A

POLLUTION CONTROL EQUIPMENT: N/A

I. EMISSION LIMITS

1. There shall be no visible emissions from EU-AUTOCLAVE1. **(R 336.1301(1)(c), R 336.1901)**

II. MATERIAL LIMITS

1. The permittee shall not treat any waste in EU-AUTOCLAVE1 other than 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 EU-AUTOCLAVE1 specifically prohibited under the Medical Waste Regulatory Act, Part 138, 1978 P.A. 368, as amended.[1] **(R 336.1901)**

2. 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.[1] **(R 336.1901)**

3. The permittee shall not treat any waste containing mercury[1]. **(R 336.1224, R 336.1225)**

III. PROCESS/OPERATIONAL RESTRICTIONS

1. The permittee shall not operate EU-AUTOCLAVE1 unless the Waste Management Plan (WMP), specified in Appendix A, and the Preventative Maintenance/Malfunction Abatement Plan (PM/MAP), specified in Appendix B, or an alternate plans approved by the AQD District Supervisor, are implemented and maintained. If a 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 EU-AUTOCLAVE1 in a satisfactory manner, and a program for corrective action for such events.[1] **(R 336.1901)**

2. The permittee shall not operate EU-AUTOCLAVE unless the temperature achieved during the cooling cycle is less than or equal to 80.0°C and the vacuum pressure of the evacuation cycle is less than -5.80 psi.[1] **(R 336.1224, R 336.1225)**

IV. DESIGN/EQUIPMENT PARAMETERS

1. The permittee shall install, maintain and operate, in a satisfactory manner, a device to monitor and record the temperature of the cooling cycle and the pressure during the vacuum cycle, on a per-batch basis, to comply with SC III.2.[1] **(R 336.1224, R 336.1225)**

V. TESTING/SAMPLING: N/A

VI. MONITORING/RECORDKEEPING

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

1. The permittee shall monitor, in a satisfactory manner, the description of waste treated in EUAUTOCLAVE on an as-treated basis.[1] **(R 336.1901)**

2. The permittee shall keep, in a satisfactory manner, records of the cooling temperature, evacuation pressure, time and description of waste treated for EU-AUTOCLAVE1. All records shall be kept on file at the site and made available to the Department upon request.[1] **(R 336.1901)**

3. The permittee shall keep record of, for all waste processed, a certification from the waste generator including[1]
   i) A statement indicating that "This waste does not contain mercury."
   ii) The certifying party's name or identification number
   iii) The certifying party's contact information
   (R 336.1901)

VII. REPORTING: N/A

VIII. STACK/VENT RESTRICTIONS: N/A

1. The permittee shall vent no portion of EU-AUTOCLAVE1 to the outside air[1]. **(R 336.1224, R 336.1225, R 336.1901)**

IX. OTHER REQUIREMENTS: N/A

Footnotes:
[1]This condition is state only enforceable and was established pursuant to Rule 201(1)(b).

APPENDIX A

Medical Waste Management Plan

August 31, 2012

TreatMed GREEN Biomedical Waste Treatment Facility (TGBWTF)

Prepared by:

TreatMed, Inc.

Prepared for:

Mr. Andrew L. Shannon
Environmental Quality Analyst

Michigan Department of Environmental Quality
Resource Management Division
525 West Allegan Street
Lansing, MI 48933

Tel: (517) 335-1146
Email: MedicalWaste@michigan.gov

Table of Contents

Contact Information

Alex Squalli, P.E.

Vice President, Business Operations

1400 Hubbell Place, Suite 1206, Seattle, WA 98101

Phone: (206) 427-6641

Email: asqualli@treatmed.com

Web Site: www.treatmed.com

Introduction

The main operation of the proposed *TreatMed GREEN Biomedical Waste Treatment Facility (TGBWTF)* is to collect, process, and sterilize the infectious medical waste generated from healthcare institutions with the principal focus to provide services to customers in the state of Michigan.

In accordance with the requirements of the ***Medical Waste Regulatory Act of the Michigan Public Health Code*** mandated by ***Michigan Department of Environmental Quality (MDEQ),*** this *Medical Waste Management Plan* outlines and addresses TreatMed's procedures, framework, responsibilities, policies, and practices regarding the safe handling, collection, transport, storage, treatment, and disposal of the infectious waste at TreatMed facility.

It is the policy of TreatMed to protect the health, safety, and quality of life of its employees and the public, and to encourage employees to exercise best practices at all times. All TreatMed's personnel are required to read all relevant operation and safety manuals/procedures, and complete all required training. Employees shall also adhere to emergency response measures as well as to reporting and recordkeeping guidelines that include reporting any accidents/incidents, unsafe work practices, or safety hazards.

Regulatory Authorities and RMW Statutes

Present Regulatory Overview

Medical waste regulations are enacted by federal, state, and local authorities to enforce the proper management and disposal of the infectious medical waste and to ensure public safety and environmental protection. Federal, state, and local laws require Regulated Medical Waste (RMW) to be treated and rendered non-infectious before it can be disposed of as solid municipal waste. It is unlawful to reduce, reuse, or recycle any infectious waste prior proper treatment and disposal. The following is a brief summary of regulatory authorities that play a central role in regulating the handling and disposal of the medical waste:

- Michigan Department of Environmental Quality (MDEQ)
  - Air Quality Division (AQD)
  - Resource Management Division: Medical Waste Regulatory Program (MWRP)
- Local Regulations
- The Environmental Protection Agency (EPA)
- Department of Labor (DOL)
  - Occupational Safety and Health Administration (OSHA)
- Department of Transportation (DOT)
- Department of Health and Human Services (DHHS)
  - Centers for Disease Control and Prevention (CDC)

Authorization and Permitting

As a commercially operated RMW treatment facility, TGBWTF shall comply with federal, state, and local permitting requirements that administer management and disposal of RMW. These requirements oversee RMW packaging, labeling, collection, transport, storage, treatment, and disposal. Prior being in service, TGBWTF shall be permitted by MDEQ as a Regulated Medical Waste Treatment Facility.

Authorized and Prohibited Medical Waste

Categories of Medical Waste

Medical waste is all waste materials generated at healthcare facilities, such as hospitals, clinics, physician's offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories.

The Medical Waste Tracking Act of 1988 defines medical waste as "any solid waste that 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." Medical waste can be classified into one of the following four main categories:

1. **General Solid Waste** is garbage that is usually disposed of as municipal solid waste. This includes recyclable or compostable materials, as well as construction and demolition waste.
2. **Regulated Medical Waste** or **Infectious waste** is generally defined as waste that is capable of producing infectious diseases. Other terms used include: ***"Bio-hazardous Waste", "Biomedical Waste", "Biological Waste", or "Red Bags".*** This category of waste includes sharps, pathological waste, biological waste, cultures and stocks of infectious agents, animal waste, chemotherapy waste, and discarded infectious medical equipment and parts.
3. **Hazardous waste** is defined as waste that may cause or significantly contribute to mortality or serious illness or pose a substantial hazard to human health and the environment if improperly managed or disposed of. Hazardous waste is subject to federal and state regulations. Under the Resource Conservation and Recovery Act (RCRA), the waste is considered hazardous if it exhibits one or more of the four hazardous characteristics (toxic, reactive, ignitable, or corrosive), or appears on one of the four hazardous waste list (F-list, K-list, P-list, U-list).
4. **Radioactive waste** is waste that exhibits radiologic characteristics such as radioactive.

Authorized Waste

TGBWTF will accept, process, and treat all types of Regulated Medical Waste, which includes following subcategories:

1. **Cultures and Stocks:** Cultures and stocks of infectious substances and associated biological.
2. **Pathological Wastes / Anatomical Wastes:** Tissues, organs and body parts, including body fluids removed during surgery, autopsy, or other medical procedures.
3. **Human Blood, Blood Products, and other Bodily Fluids:** Discarded human blood, components or products of blood; items saturated with blood, blood products, or body fluids, or caked with dried blood.
4. **Sharps:** Sharps including syringes, pipettes, scalpel blades, vials and needles; broken or unbroken glass.
5. **Animal Wastes:** Discarded material including carcasses, body parts, body fluids, blood, or bedding from animals exposed to infectious substances.
6. **Isolation Wastes:** Discarded material contaminated with blood, excretions, etc.

7. **Contaminated Medical Equipment:** Medical equipment that was in contact with infectious substances.
8. **Surgery Wastes:** Discarded material including soiled dressings, sponges, drapes, gowns, gloves, etc.
9. **Laboratory Wastes:** Waste that was in contact with infectious substances such as slides and cover slips.
10. **Dialysis Wastes:** Effluent and equipment that was in contact with blood of patients undergoing dialysis.

Prohibited Waste

TGBWTF will not accept, process, or treat any of the following categories of medical waste:

1. **Hazardous Waste**: Any waste that exhibits one of the four hazardous characteristics or appears on one of the four hazardous waste list (e.g., drums, pails, bottles, cans, batteries, heavy metals such as Mercury, etc.) and any other containers with hazardous warning labels or symbols.
2. **Chemical Waste**: Any waste that contains hazardous chemicals (e.g., formaldehyde, acids, alcohols, waste oil, solvents, reagents, fixer, developer, etc.) This waste may be classified as hazardous waste.
3. **Radioactive Waste**: Any waste that contains radioactive materials (e.g., any container or packaging with a radioactivity level that exceeds regulatory or permitted limits.)
4. **Chemotherapy Waste**: Any waste that contains chemotherapy agents (e.g., antineoplastic and cytotoxic materials including the non-conforming U-listed chemotherapy wastes Chlorambucil, cyclophosphamide, Daunomycin, Melphalan, Mitomycin C, Streptozptocin, Uracil Mustard, etc.)
5. **Pharmaceutical Waste**: Any waste that contains expired, unused, spilt, and contaminated pharmaceutical products and drugs.
6. **Mixed Waste:** Any waste that is comprised of any mixture of infectious medical waste, hazardous waste, and/or radioactive materials.

Medical Waste Segregation, Containment, Packaging and Labeling

Segregating RMW from the rest of the generated medical waste at its point of origin is the responsibility of the generator. TreatMed expects healthcare facilities to implement all necessary segregation measures and policies that adhere to local, state, and federal RMW regulations. Specifically, both the DOT and OSHA has established legal requirements for handling, packaging, and labeling RMW to ensure public and personnel safety. Packaging and labeling requirements include the following:

- RMW shall be placed in rigid, impermeable, leak and puncture resistant red bags that shall be conspicuously labeled with the universal biohazard symbol and/or marked with the words “Infectious or Biohazard Waste”.
- Filled bags must be securely tied or sealed to prevent leakage during the handling, transport, or storage process.
- Red Bags intended for off-site transport shall be labeled and placed inside a second sealed plastic bag or within a fully enclosed, rigid, sturdy container.
- Heavier materials shall be supported in double-walled corrugated fiberboard boxes or equivalent rigid containers.

- Sharps containers must be only those containers specifically designed and manufactured for the management and/or disposal of sharps. They shall be prominently labeled with the words "Sharps" and bear the universal biohazard symbol.
- Liquids shall be contained in break-resistant, tightly sealed containers.

Standard Packaging Procedures:

The following instructions demonstrate the generator's standard packaging procedures to prepare and secure the biomedical waste for off-site transportation.

Labeling and Marking Requirements:

The outer packaging shall contain the following labeling information:

1. The name, address, business telephone and fax numbers of the generator
2. The universal biohazard symbol and/or the words "Infectious Medical Waste", "Biomedical Waste", "Biohazard", or "Regulated Medical Waste"
3. Orientation marking
4. UN Identification Number (e.g., Regulated Medical Waste, UN3291)
5. Packing Group (e.g., PG I for great danger; PG II for medium danger; PG III for minor danger)
6. Hazard Class/Division
7. Total Quantity
8. Date of shipment
9. Transporter's name and permit number
10. The name, address, and business telephone and fax numbers of the facility at which the waste is to be rendered noninfectious
11. Emergency response 24 hour telephone number

If a bag or sharps container is to be inserted into a secondary container, the larger container shall have the same appropriate labeling as described above. However, each primary container shall include the name and the address of the generator.

Biohazard Marking

Infections Substance Label

Orientation Marking

Medical Waste Collection and Transport

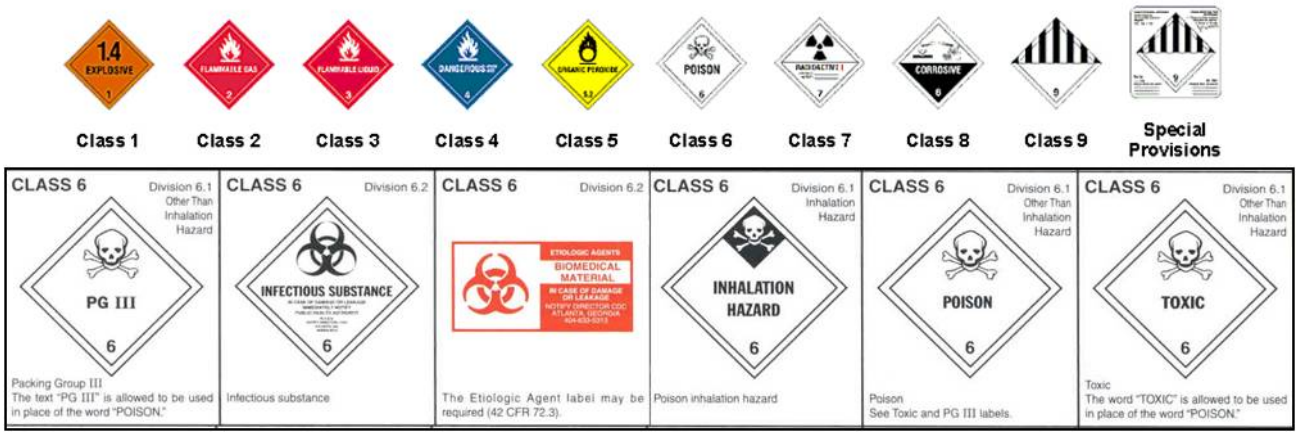
Department of Transportation (DOT) Classification of Biological Materials

The DOT main responsibility is to ensure the protection of public safety in all areas of transportation by establishing specific guidelines indicating how hazardous materials shall be prepared, packaged, labeled, and transported. A hazardous material is any substance or material that can burn, explode, react violently or cause injury or harm to people, property or the environment during transport. The DOT classifies RMW as a hazardous material. This infectious substance that is known or reasonably expected to contain pathogens is referred to as a ***Division 6.2 material***. DOT's classification and labels are delineated in Table 1 and Figure 1.

Table 1 DOT Nine Hazard Classes

Hazard Class	Division	Label	Description
Class 1	1.1-1.6	Orange	Explosives
Class 2	2.1	Red	Flammable Gases
	2.2	Green	Non-Flammable Gases
	2.3	White	Poison Gases
Class 3	N/A	Red	Flammable Liquids
Class 4	4.1	Red striped	Flammable Solids
	4.2	Red top White bottom	Spontaneously Combustible Materials
	4.3	Blue	Dangerous When Wet Materials
Class 5	5.1	Yellow	Oxidizers
	5.2	Yellow	Organic peroxides
Class 6	6.1	White	Poisons
	6.2	**White**	**Infectious Substances**
Class 7	N/A	Yellow-top White-bottom	Radioactive
Class 8	N/A	White-top Black-bottom	Corrosive
Class 9	N/A	Black striped-top White-bottom	Miscellaneous

Figure 1 DOT Nine Hazard Classes Labels



United Nations (UN) Classification

UN numbers or **UN IDs** are four-digit numbers that identify hazardous substances in the framework of international transport. UN numbers are assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods. UN numbers and categories of biohazardous agents are:

Category A

- UN 2814 (Infectious Substance, Affecting Humans)
- UN 2900 (Infectious Substance, Affecting Animals)

Category B

- UN 3373 (Diagnostic Specimen *or* Clinical Specimen *or* Biological Substance)
- **UN 3291 (Regulated Medical Waste)**

Figure 2 UN Division 6.2 Package – Category A & Category B

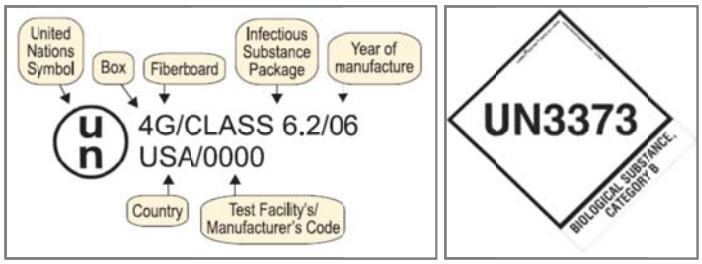
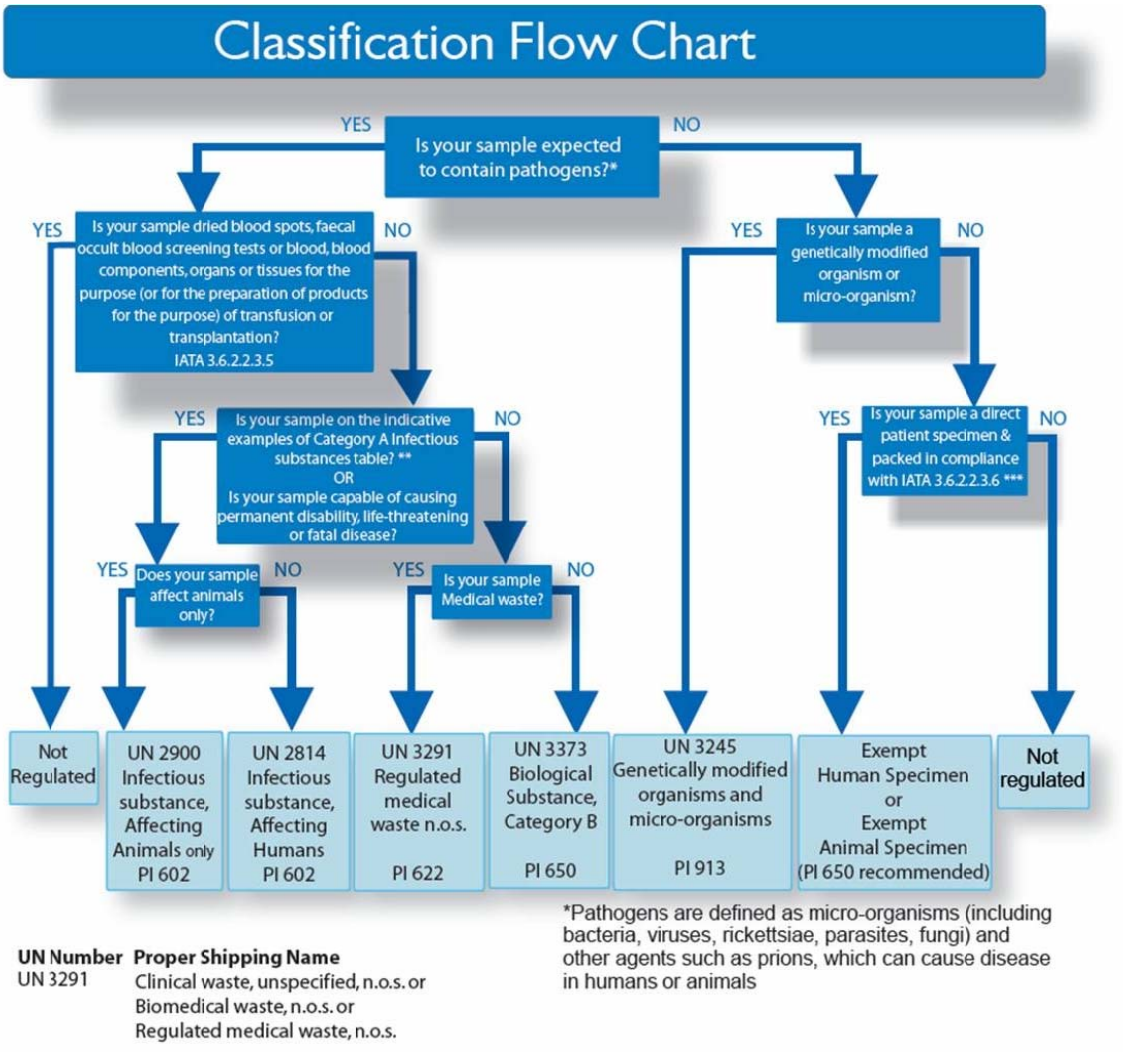


Figure 2 and Figure 2 portray the classification process of the infectious waste as well as the UN specification marking of Category A and Category B.

Figure 3 RMW Classification Flow Chart



RMW Transport Packaging

Packaging for RMW must meet UN specifications for performance standards, weight restrictions, marking, and transport requirements as defined in 49 CFR. For medical waste pick up and transport, TreatMed will be employing 200 gallon (Red color coded) reusable medical waste wheeled Bins.

RMW Transport Guidelines

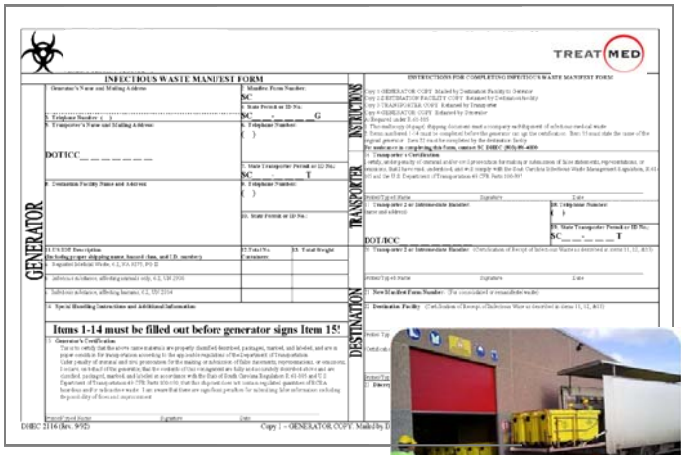
Transportation of biomedical materials is governed by *49 CFR,* which derives its authority from the ***Hazardous Materials Transportation Uniform Safety Act***. The intent of RMW transport regulations is to prevent accidental exposure of personnel handling the infectious waste, protect the safety of the public, and reduce environmental impact.

TreatMed shall not perform any RMW collection or transport services without a valid RMW transport permit. TreatMed's authorized collector shall adhere to all applicable laws and regulations including but not limited to DOT and OSHA standards and their safety measures. TreatMed will only accept infectious waste that has been properly segregated and packaged in approved DOT containers. In addition to mandated packaging requirements, TreatMed's transporter will be performing *Inspection and Controls Tests* prior transporting any RMW.

Medical Waste Acceptance

RMW Manifest Form / Transport & Tracking Form

Prior any RMW pickup, transfer, or transport, TreatMed's collector shall generate and complete the ***RMW Manifest Form.*** This ***Transport and Tracking Form*** records and monitors all RMW management operations from the collection site to TGBWTF then to its final disposal destination at an authorized municipal landfill ensuring that the collected infectious waste is properly treated and safely disposed of.


INFECTIOUS WASTE MANIFEST FORM

TREAT MED

GENERATOR

TRANSPORTER

DESTINATION

Items 1-14 must be filled out before generator signs Item 15!

Incoming Medical Waste Acceptance - Waste Inspection and Scan Test

Medical Waste *Acceptance and Inspection/Scan Test* is a mandatory procedure that is performed upon receiving medical waste from either an authorized hauler or TreatMed collector. The entire medical waste management process shall be performed using universal precautions, even when the handler is fully trained and reasonably assured that the wastes are safe for handling. Incoming waste shall also meet DOT applicable standards of 49 CFR Parts 171-180 or Parts 100-397.

During the offloading process TreatMed personnel are instructed to:

1. Verify the completed manifest's information including generator's data, waste categories, and capacity.
2. Visually inspect incoming containers for signs of leakage or improper packaging.
3. Check for unacceptable waste and verify radiation counts to be below background levels by scanning incoming waste with an approved handheld radioactive scanner that is set to alarm at a background level. The scanning should be performed within six inches from the sides of the container; if unacceptable substances are detected, the waste will be managed according to Non-conformity Waste Response procedures described below.
4. Confirm manifest's information using an automated scale and barcode reader located at the receiving dock or at conveyor station. Generator's and weight's data pertinent to each accepted package, will be automatically collected and stored to track/ensure that RMW is managed properly and is not stored for periods that exceed the temporary storage requirements of twenty (20) days or ninety (90) days storage period from the time the container is initiated at the producing facility.
5. If necessary generate a tag with a barcode for storage waste bins where small packages or containers of RMW have been transferred to.

Non-conformity Waste Response

If non-conformity waste is noted during inspection, the respective material shall be handled as follows:

- If a problem associated with the waste packaging is discovered, facility personnel will correct the issue (e.g., re-seal a box that may have opened during transit; or repackage a damaged container of waste).
- If leaking packages are identified that cannot be readily corrected, facility personnel will follow procedures described in *TreatMed's Contingency Plan and Emergency Response*.
- If a load of an unacceptable waste (other than radioactive) is detected during unloading/check-in process, facility personnel shall isolate the identified hazardous materials and shall contact transporter/generator to remove the unaccepted waste.
- In the presence of radioactive materials at any detection above background radiation, TreatMed personnel shall immediately set the waste aside in the isolation area and report the incident to the Site Manager and TreatMed EHS. TreatMed shall notify MDEQ and contact the generator/transporter to arrange for return of the rejected load. The generator is responsible for handling the rejected load and shall held the radioactive materials for decay in generating facility storage area until the radioactivity cannot be distinguished from the background radiation level. At this point, the generator is authorized to haul the decayed material to TreatMed facility to be processed as RMW. TreatMed shall not collect or accept any wastes that indicate the presence of radioactive material at any level above background radiation. UNDER NO CIRCUMSTANCES will TreatMed knowingly accept or process any waste emitting radiation in levels greater than regulatory limit.

For either of the above cases, the concerns regarding the load will be recorded on the inspection form and written notification will be provided to the transporter/generator. If repeat problems persist with a transporter or generator, the responsible party will be required to submit a preventive and corrective action plan to ensure that delivered materials are properly packaged and hauled to TGBWTF. Transporters/generators that fail to correct identified problems will be banned from making future deliveries to the facility and will no longer be considered a customer or a partner.

ECODAS RMW Treatment Process and System Overview

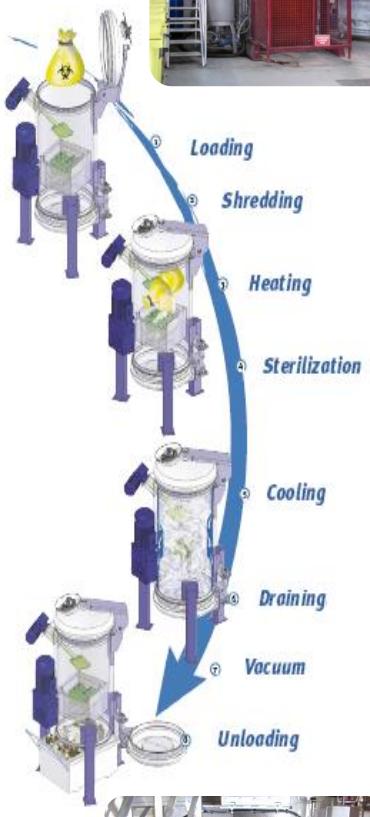
Experience and Qualifications

Since 1993 ECODAS has been designing, manufacturing and supplying customers worldwide with automated solutions for medical waste treatment. The ECODAS Sterilizer SYSTEMS (ECODAS SYSTEMS) are an alternative non-burning medical waste patented treatment technology based on a fully automated autoclaving process combined with an advanced integrated pre-shredding design.

For more than twenty years ECODAS team has leveraged a wide expertise in designing and manufacturing of pressurized and automated thermal machines to provide high value medical waste treatment solutions using green technology. Today, with 281 ECODAS SYSTEMS installed in 62 countries, ECODAS SYSTEMS are well known worldwide for superior performance in terms of safety, durability, reliability, and effectiveness.

Treatment Cycle and Operating Characteristics

- The ECODAS T2000 SYSTEM processes about 688 lb. of RMW per 45 min cycle (2,500 liters per 45 min cycle). This is equivalent to a daily waste capacity of 5,228 lb. (2.6 tons) or an annually weight capacity of 1,908,053 lb. (954 ton) operating 1 shift.
- ECODAS patented GREEN process combines shredding and direct pressurized heated steam; all in one (1) enclosed system with no intermediate handling steps to treat the waste. The ECODAS process subjects the biomedical waste to a minimum temperature of 138 °C / 280 F with a consequential average pressure of 3.5 Bars / 55 psi of direct heated steam (Microbial inactivation of 6-8log10).
- The machine is vertically designed and positioned for waste to be automatically loaded form the top into the upper storage chamber. Once the system is closed and sealed, the treatment cycle is launched; the waste is shredded and lowered into the retention chamber at the bottom of the machine for steam sterilization. After all the treatment parameters are automatically validated, the interlocked system releases opening the bottom door. Thereafter, the neutralized waste is unloaded into a trash bin placed directly underneath the unloading door. It is important to point out that the storage chamber, the shredder, and the retention chamber are entirely sterilized with every treatment cycle, and in doing so, the operator is not exposed to any safety hazards.
- The system's operating sequence is critical to ensure delivering effective biomedical waste treatment process. The internal and built-in shredder ought to run prior the sterilization phase in order to guarantee steam penetration into the dissected infectious materials.
- The operation of the ECODAS SYSTEM and the sequence of steps are fully



computerized and controlled by a Programmable Logic Controller (PLC).

- The system renders the waste unrecognizably neutral with 80 % volume reduction in one, fully automated cycle/step.
- The treatment process is completed in one step form load to unload circumventing any intermediate handling of the waste either manually or automatically through conveyance and other complementary equipment. The ECODAS SYSTEM does not require any consumables (e.g. autoclavable bags, liners, chemical/disinfection products, packages, printing labels) or any supplementary equipment (e.g. autoclavable carts, conveyors, external shredder).

Waste Disposal

Upon the completion of an approved sterilization cycle, the treated waste is unloaded directly into a municipal garbage cart. The disposal carts are emptied onto a roll-off dumpster for a final landfill transfer and disposal. The final neutralized waste is unrecognizable solid material that is volume reduced by about 80% of its initial volume. To monitor the disposal process, *Treated Waste Disposal Tracking Forms* shall be completed and retained for record keeping.

Enhanced Safety Features

- Built-in security features guaranteeing that all treatment conditions are achieved prior unlocking and opening the system's unloading door to release the treated waste. Temperature, pressure, and exposure time are continuously monitored and maintained throughout the computerized process.
- Database and information security are guaranteed through password protected programs that confirm the integrity, the validity, and the protection of the operating process/parameters.
- For each treatment cycle, the operating results of essential data parameters are automatically printed, digitally stored, and securely protected for internal or external review.
- Recorded data include cycle number, treatment step, cycle ok status, and treatment parameters such as exposure time, chamber temperature, steam pressure, and waste temperature.

Computerized Guide User Interface

- The whole operations and sequences of the ECODAS SYSTEM are entirely computerized and regularly controlled by an advanced programmable microprocessor offering reliable, simple, consistent, and safe treatment process. This Programmable Logic Controller monitors, regulates, and maintains the operating parameters during the entire length of each automated treatment cycle.
- The ECODAS SYSTEM also features forward-thinking interactive design and diagnostic features via a Guided User Interface (GUI) enabling the operator to interface effortlessly with the unit and follow commands to operate and maintain the system as well as to troubleshoot errors and repair anomalies. This highly-developed touch screen system also

support cycle's progress display, configuration, setup, maintenance, troubleshooting, alarms alert, and step-by-step diagnostics assistance.

- The system is fully automated and comprehensive allowing very minimum handling of medical waste, with NO contact with the infectious waste during the treatment cycle.
- The ECODAS SYSTEM guarantees secure, safe, and reliable process by monitoring, recording, and safeguarding all operating characteristics and treatment data through password-protected protocols.

Training Programs

In accordance with ***MDEQ Medical Waste Regulatory Program*** guidelines, TreatMed is responsible for training and protecting its personnel, TreatMed will be providing all necessary resources and Personal Protective Equipment (PPE) to its employees to ensure that RMW is handled, stored, treated, and disposed of properly and safely.

TreatMed's personnel handling and managing RMW shall receive occupational, technical, and safety training in line with their responsibilities and duties. Appropriate personnel will be identified by supervisors according to workplace safety assessments to undergo explicit training.

All personnel are responsible for adhering to all policies, processes, and procedures described in TreatMed's operational and safety manuals. TreatMed's training will include the following set of programs:

Bloodborne Pathogens and RMW Safety Training

- In accordance with the requirements of OSHA, TreatMed shall provide Bloodborne Pathogens training to personnel who are handling RMW or may be exposed to infectious materials. The training shall address all required elements described in the Bloodborne Pathogens Standard, including universal precautions, exposure response, post-exposure follow-up, reporting, and recordkeeping.
- TreatMed shall provide safety training including biosafety, spill exposure, and emergency response to personnel with duties of managing biological waste.

Equipment Training: Installation, Maintenance, Operation, and Diagnostics

- Installation and equipment routine operation training shall be offered either independent of or in conjunction with, equipment start-up and commissioning by the manufacturer, its distributor, or local representative at TGBWTF. Some of the training may be provided at the manufacturer's site based on the reference manual supplied for the machine or other system manuals recommended by the manufacturer in conjunction with maintenance and diagnostic procedures.
- TreatMed is responsible to train and qualify its staff to operate ECODAS T2000 SYSTEM. Operator shall be provided specific training on the safe and proper use of the system following manufacturer's instructions. A qualified operator shall understand basic sterilization conditions, the importance of exposure time, temperature, and pressure relationships and any other parameters required for proper RMW treatment.
- Advanced training programs shall be provided in order to familiarize and enhance the competency of TreatMed's maintenance technicians in the operation, maintenance, and troubleshooting of ECODAS SYSTEMS. This course is a three (3) days comprehensive, formal curriculum that covers maintenance and diagnostic procedures. Other combination of classrooms and field work simulating actual use of the system shall be offered as needed.

- Personnel who conduct efficacy testing of ECODAS T2000 shall also be trained to follow approved and effective standard operating procedures and spore test instructions.

RMW Handling and Transport Training

In accordance with RMW mandated guidelines and abiding by MDEQ, DOT, and OSHA standards, TreatMed shall provide all its employees handling RMW a comprehensive training on how to handle, manage, transport, store, treat, and dispose of RMW. This training shall include:

- General awareness
- Function specific:
  - Packaging / Labeling
  - Handling / Transport
  - Manifest / Recordkeeping
  - RMW Acceptance Test: RMW Inspection and Scan Test
  - Storage
  - Vehicle inspection and disinfection
  - Safety, spill control, and emergency response

Annual Training & Recordkeeping

TreatMed personnel shall receive training prior performing any initial job duties. Employees handing biomedical waste are required to participate in annual up-to-date sessions to keep them current on all operating procedures and mandated RMW regulations. Other retraining programs shall be conducted every three (3) years as required by *49 CFR*. All training shall be appropriate to the responsibilities associated with employee's position and shall be performed by instructors who are knowledgeable and experienced with the subject matter.

TreatMed administrative office shall retain all training records and shall be readily available to MDEQ and to other regulatory agencies as required. Training records will include:

- Employee's name and job title
- Certificate number (if applicable)
- List of courses or training
- Respective dates of training

Facility Safeguard & Universal Precaution

Facility Safeguard

Vicinity Access Control

Vicinity access control is established to protect the public and minimize exposure to RMW. During non-operating hours vicinity door of areas containing RMW shall be shut and locked. During operating hours, only authorized TreatMed personnel shall access the vicinity either through a secure door lock or through an access control system.

Occupation Signage

Occupation signage and label procedures shall be posted in all areas where potential injuries or hazards are probable. This signage shall provide warnings and remind TreatMed employees and visitors to proceed with cautions. Biohazard labels and safety signs shall be posted on doors or entrances of RMW working area to communicate hazards pertinent to infectious materials. All equipment that may inflect injuries shall also contain prominent safety signage. Signage will include the following information as applicable:

- Biosafety and/or warning sings
- Supervisor's or other responsible person's name
- Emergency contact information
- Safety and/or operation procedures

Universal Precautions

Universal Precautions describe a range of operational and engineering controls designed to enhance safety and eliminate or minimize employee injuries and exposure to RMW. TreatMed employees, contractors, and visitors shall conform to Universal Precautions and exercise good working practices and safety measures that include the following (in no particular order or priority):

1. Supervisors shall maintain adequate working conditions, restore or overhaul any decrepit materials, and retrofit any aged or worn equipment.
2. Supervisors shall ensure that all occupational and safety measures are to be met.
3. Supervisors shall provide employees with all necessary equipment including PPE and spill control kits; it is the managers' responsibility to ensure that employees are trained to use properly all equipment and to adhere to all safety guidelines.
4. Employees shall conform to all RMW regulatory guidelines, TreatMed policies, and work practices.
5. Employees shall follow sanitary measures and ensure that the facility is maintained in a clean and sanitary condition. All contaminated equipment and working surfaces shall be decontaminated and washed instantly after being in contact with RMW.
6. Employees shall not shear off, break, bend, recap, or remove contaminated RMW. They shall not be in direct contact with RMW except during spill occurrence at which employees shall use proper PPE and adhere to spill response and cleanup procedures.
7. Employees shall not operate any damaged or faulted equipment or devices and shall request immediate fix or replacement of any malfunctioning systems.
8. Punctured, torn, broken or damaged container shall not be used for any operation and it shall be discarded.

9. Biomedical waste must be handled in a manner to protect employees, public, and the environment.
10. Employees shall never compress or compact untreated RMW. If RMW are to be carried manually, employee must hold bag away from body and shall never place a bag over shoulder for carriage.
11. All bins, pails, cans, and similar receptacles intended for reuse shall be washed, decontaminated, and inspected on a regular basis.
12. Employees shall adhere to Biosafety program and shall use proper PPE as required.
13. Under no circumstances will a RMW container be disposed of in regular trash.
14. TreatMed personnel shall comply with RMW packaging weight limits and shall never overfill a load as the overloaded package presents lifting hazards and increase the risks of RMW spill and exposure.
15. Under no circumstances employees may breach safety procedures or bypass equipment safety interlock systems.
16. Eating and drinking is prohibited in working areas where there is reasonable likelihood of infectious waste exposure. Food and drink shall not be kept in areas where RMW is present.
17. Using Tabaco products are strictly prohibited on facility premises.

Recordkeeping and Reporting

The tasks of reporting and recordkeeping are the responsibility of the facility manager or TreatMed administrative person; however, TreatMed's personnel are responsible for ensuring that operation and treatment records are managed as specified in this document. All records and reports shall be maintained at the facility and be readily available to MDEQ and to other regulatory agencies for review upon request. Records shall always include operator and supervisor names, initials, dates, test or performance results, and remarks if applicable. Records shall also follow good and correct documentation practices (e.g., anytime an employee makes an entry in any logbook, the entire form must be filled in without leaving blank statements. N/A, cross-lining, or initializing, and dating blank entries should be adopted at all time).

According to TreatMed processes and abiding by ***MDEQ Medical Waste Regulatory Program*** guidelines, the following records must be managed and maintained for at least three (3) years:

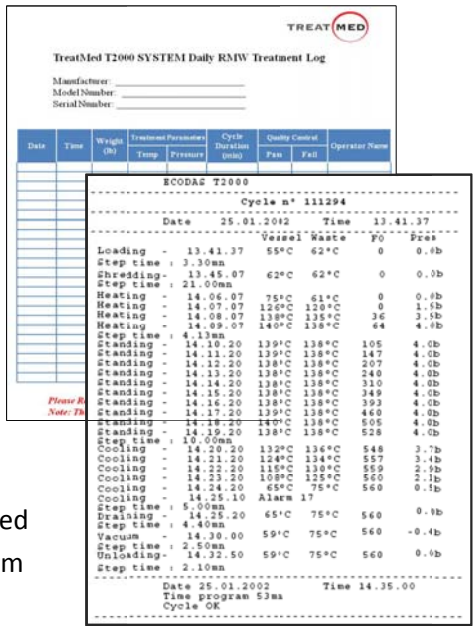
Training Records

All training shall be recorded and maintained for internal and/or external review. Training shall include but not limited to the following:

- Safety and compliance training including bloodborne pathogens training
- Equipment training: Installation, maintenance, operation, and diagnostics

- Management, handling, transporting, storing, and treating of RMW

Figure 4 T2000 Daily RMW Treatment Log


TREATMED

TreatMed T2000 SYSTEM Daily RMW Treatment Log

Manufacturer: _____
Model Number: _____
Serial Number: _____

Date	Time	Weight (lb)	Treatment Parameters		Cycle Duration (min)	Quality Control		Operator Name
			Temp	Pressure		Pass	Fail	

ECODAS T2000

Cycle n° 111294

Date 25.01.2012 Time 13.41.37

		Vessel	Waste	F0	Pres
Loading -	13.41.37	55°C	62°C	0	0.0b
Step time : 3.30mn					
Shredding-	13.45.07	62°C	62°C	0	0.0b
Step time : 21.00mn					
Heating -	14.06.07	75°C	61°C	0	0.0b
Heating -	14.07.07	126°C	128°C	0	1.5b
Heating -	14.08.07	138°C	135°C	36	3.5b
Heating -	14.09.07	140°C	138°C	64	4.0b
Step time : 4.13mn					
Standing -	14.10.20	139°C	138°C	105	4.0b
Standing -	14.11.20	139°C	138°C	147	4.0b
Standing -	14.12.20	138°C	138°C	207	4.0b
Standing -	14.13.20	138°C	138°C	240	4.0b
Standing -	14.14.20	138°C	138°C	310	4.0b
Standing -	14.15.20	138°C	138°C	349	4.0b
Standing -	14.16.20	138°C	138°C	393	4.0b
Standing -	14.17.20	139°C	138°C	460	4.0b
Standing -	14.18.20	140°C	138°C	505	4.0b
Standing -	14.19.20	138°C	138°C	528	4.0b
Step time : 10.00mn					
Cooling -	14.20.20	132°C	136°C	548	3.7b
Cooling -	14.21.20	124°C	134°C	557	3.4b
Cooling -	14.22.20	115°C	130°C	559	2.9b
Cooling -	14.23.20	108°C	125°C	560	2.1b
Cooling -	14.24.20	65°C	75°C	560	0.1b
Cooling -	14.25.10	Alarm 17			
Step time : 5.00mn					
Draining -	14.25.20	65°C	75°C	560	0.1b
Step time : 4.40mn					
Vacuum -	14.30.00	59°C	75°C	560	-0.4b
Step time : 2.50mn					
Unloading-	14.32.50	59°C	75°C	560	0.4b
Step time : 2.10mn					

Date 25.01.2002 Time 14.35.00
Time program 53mn
Cycle OK

Operating Records

Operating records will include the following documents:

- Operating permits and approvals
- RMW Manifest Forms / Transport and Tracking Forms
- Inspection Logs: Maintenance, and Quality Control Reports
- TreatMed Medical Waste Management Plan and operating and safety manuals
- ECODAS SYSTEM Instruction Manual: Installation, Operation , and Maintenance

Treatment Records

An automated log report shall be generated for every treatment cycle performed by ECODAS T2000 Sterilizer. ECODAS SYSTEM's operator shall verify and confirm all treatment parameters and shall approve each RMW treatment cycle on *TreatMed T2000 SYSTEM Daily RMW Treatment Log* by dating and initializing the report.

Incidents Reports, Emergency Response, and Spill Exposures

According to MDEQ guidelines and to TGBWTF emergency response and spill exposure procedures, TreatMed is responsible for documenting, reporting, and maintaining RMW exposure incident, post-exposure action plans, and personnel's authorized records.

Biosafety Program and Bloodborne Pathogens Exposure Control

The Biosafety Program aims to protect TreatMed personnel, the public and the environment from RMW hazards and occupational injuries. Because TreatMed working environments could pose infectious disease and other risks to personnel handling RMW, TreatMed requires the use of biosafety guidelines and safety precautions in order to reduce or eliminate the risk of RMW exposure and potential contamination of the workplace. TreatMed personnel handling infectious waste shall receive annual bloodborne pathogens training and shall comply with all preventive procedures, exposure response policies, post-exposure follow-ups, reporting, and recordkeeping guidelines.

Bloodborne Pathogens Definition

Bloodborne pathogens are infectious materials in blood that can cause disease in humans, including hepatitis B and C and human immunodeficiency virus, or HIV. Workers exposed to these pathogens risk serious illness or death. Anytime there is "blood-to-blood" contact with infected blood or other potentially infectious materials, there is potential for transmission. Exposure to RMW (blood, body fluids, and body secretions) can occur by **direct contact, indirect contact** and/or by **occupational injury:**

- **Direct transmission** – It occurs when infected blood enters bloodstream through an open cut, abrasion, sore, acne, damaged or broken skin such as blisters or sunburn, mucous membranes of the

eyes, nose, or mouth

- **Indirect transmission** – It occurs when a contact of contaminated object or surface takes place and a transfer of infection to mouth, eyes, nose, or open skin ensue.
- **Occupational injury** – It occurs when a contact with blood or other potentially infectious materials that may result from employees' daily occupational duties.

While handling RMW, safety precautions concerning bloodborne pathogens must be taken during all operations. Employees are required to comply with TreatMed safety guidelines and shall employ the necessary PPE prior handling any infectious materials.

Bloodborne Pathogens Exposure Control

To protect workers whose jobs put them at a reasonable risk of coming into contact with blood and other potentially infectious materials, TreatMed bloodborne pathogens standard aims to reduce the significant risk of infection by establishing the following guidelines:

1. *TreatMed Waste Management Plans, Operation and Safety Manuals* shall include safety measures to eliminate or minimize employee exposures. TreatMed shall update the plan annually to reflect technological changes that will help eliminate or reduce exposure to bloodborne pathogens.
2. Use engineering controls by utilizing devices that isolate or remove the bloodborne pathogen hazard from the workplace.
3. Enforce work practice controls that reduce the likelihood of exposure by changing the way a task is performed. These practices include appropriate procedures for handling RMW, responding to spill, etc.
4. Provide Personal Protective Equipment such as gloves, gowns, goggles, and masks. TreatMed shall clean, repair, and replace this equipment as needed.
5. Make available Hepatitis B vaccinations to all employees with occupational exposure to bloodborne pathogens within 10 days of assignment. As part of the staff wellness program, TreatMed will encourage employees to take these vaccinations regardless of "low or no-risk" status.
6. Provide post-exposure follow-up to any worker who experiences an exposure incident. This includes conducting laboratory tests, providing confidential medical evaluation, and counseling.
7. Use signs and warning labels to communicate potential hazards and to mandate restrictions.
8. Offer training to personnel on initial assignment, and on annual bases. All information and training shall be up-to-date and shall cover bloodborne pathogens exposure risks, preventive practices, and post-exposure procedures.
9. Maintain employee medical and training records including injury log unless classified as an exempt industry under OSHA's standard on *Recording and Reporting Occupational Injuries and Illnesses*.

Personal Protective Equipment

PPE is used to protect personnel from contact with hazardous materials and infectious agents. Wearing protective clothing is an essential practice for all persons entering TreatMed RMW areas. Based on risk assessment and depending on the containment level, protective clothing

may vary from one TreatMed's vicinity to another. Standard precautions (which include universal precautions) shall be followed to reduce the risk of transmission of organisms from both recognized and unrecognized sources of infection. Personal protective devices, safety equipment, and training in the proper use of these devices and equipment shall be provided to all TreatMed employees under the appropriate circumstances. The protective clothing and equipment selected should be determined in part by the nature of the work being performed. TreatMed's personnel are responsible for the proper use of PPE. Equipment that is considered to be PPE includes, but is not limited to:

Body Protection - This category includes garment, laboratory coats, smocks, scrub suits, and gowns.

- Long sleeved garments shall be used to minimize the contamination of skin or street clothes and to reduce shedding of microorganisms from the arms.
- In circumstances where it is anticipated that splashes may occur, the garment shall be resistant to liquid penetration to protect clothing from contamination.
- Disposable clothing shall be available for visitors, maintenance and service workers in the event it is required. All contaminated protective clothing shall be discarded after every use.

Hand Protection - Gloves must be selected on the basis of the hazards involved and the conducted activities.

- Gloves shall be worn when handling RMW and shall be disposed of when contaminated, or when work with infectious materials is completed. Disposable gloves must not be washed or reused.
- Temperature-resistant gloves shall be worn when handling hot material, dry ice or materials being removed from cryogenic storage devices.
- Delicate work requiring a high degree of precision dictates the use of thin walled gloves.
- When working with hazardous materials, the lower sleeve and the cuff of the laboratory garment shall be overlapped by the glove. A long sleeved glove or disposable arm-shield may be worn for further protection of the garment.

Face Protection - Goggles or safety glasses with solid side shields in combination with masks, or chin length face shields or other splatter guards are required for anticipated splashes, sprays or splatters of infectious or other hazardous materials to the face.

Foot Protection - Appropriate shoes shall be worn to protect against spills and potential injuries. During spill response, show covers or disposable boots shall be worn.

Respirators Protection – Respiratory Protection may be necessary based on the hazard or the protection factor required.

First Aid Kits shall be available for the treatment of minor skin abrasions in the work area. TreatMed shall consider whether employees need formal training in first aid and CPR.

Spill Kits shall be available at the facility and on each vehicle transporting RMW for containment and spill's clean up.

Eyewash or Facewash Stations shall be located within the RMW handling areas and shall be checked weekly for correct operation.

Safety Showers shall be mounted within the RMW handling area and shall be straightforwardly accessible via a large chained ring that can be easily found especially during emergencies when employees may have limited vision. Showers shall be checked annually for correct operation.

APPENDIX B

Preventive Maintenance/Malfunction Abatement Plan (PM/MAP)

Installation, maintenance, service, and repair of the ECODAS SYSTEM can only be performed by ECODAS authorized, trained and certified technicians who are knowledgeable about the system. Maintenance technicians have access to perform calibration, instrument adjustment, and diagnostic functions.

TreatMed authorized technicians can also manually step through the controls without disabling any alarm or safety device installed by the manufacturer. During maintenance and repairs, particular attention must be directed to the safety instructions contained in the Instructions Manual provided by ECODAS.

TreatMed personnel shall adhere to all manufacturer's instructions during all operations and system maintenance or repair.

TreatMed will be only using original parts and accessories provided by the manufacturer or its distributors. Spare parts and accessories not supplied by ECODAS have not been tested or authorized and the use of such equipment is therefore unacceptable.

Assurance Procedures and Quality Control Program

RMW regulations require that all treatment systems used for sterilization of medical waste be subject to a routine Quality Assurance (QA)/Quality Control (QC). These programs require that all equipment be in good working conditions and capable of neutralizing all potentially infectious agents present in the waste. In addition to theTreatMed validation program that includes Installation Qualification (IQ), Operation Qualification (OQ), and performance qualification, TreatMed T2000 SYSTEMS shall be monitored using ongoing quality assurance procedures correlated with the following QC tests:

- Monthly QC spore test
- Annual QC calibration

TreatMed shall perform annual treatment parameters calibrations and spore tests to verify that the ECODAS SYSTEMS are operating properly. TreatMed shall also perform QC tests after each equipment installation, modification, or repair. The calibration and maintenance of the ECODAS Sterilizer will be conducted according to manufacturer's recommended maintenance schedule and procedures.

All test results shall be documented for each system log book and be retained for at least 3 years. These records shall be available for MDEQ and other regulatory authorities for review as requested.

ECODAS Preventative Maintenance Schedule

Machine Area	Action	Frequency
Loading Cover		
	Check if there is residue or buildup on the cover seal	Every cycle
	Clean the gasket	Every week
Cooling Water System		
	Clean the water piping system	Every 3 months
Paddle Assembly		
	Check the oil level of paddle gearbox and refill with Mystic Gear 80/90 oil if necessary	Every 6 months
	Clean the paddle assembly	Every week
High Efficiency Filter		
	Change the filter	Once a year or if Alarm 12 is ON
Shredder		
	Check the grease level of the shredder greasing pump and refill with recommended grease if needed	Every day
	Clean the shredder blades	Every week
	Check the oil level of the shredder gearbox and refill with Mystic Gear 80/90 oil if necessary	Every month
Lower Chamber		
	Clean traps	Every cycle
	Clean hopper	Every week
	Clean the waste temperature probe	Every day
Unloading Cover		
	Check if there is residue or buildup on the cover seal	Every cycle
	Clean the bottom of the cover	Every day
	Clean the inflatable seal	Every week
	Clean the drain screen	Every week
	Clean level sensor	Every week
Electrical Panel		
	Clean the fan filter	Every month

Equipment Training: Installation, Maintenance, Operation, Diagnostics, and Inspection

TreatMed is responsible to train and qualify its staff to operate, maintain, and troubleshoot ECODAS T2000 SYSTEM. Operator shall be provided specific training on the safe and proper use of the system following manufacturer's instructions and *TreatMed Waste Management Plan.* TreatMed administrative office shall retain all training records and shall be readily available to MDEQ and to other regulatory agencies as required.

Recordkeeping and Reporting Quality

TreatMed's personnel are responsible for ensuring that operation and treatment records are managed as specified in *TreatMed Waste Management Plan*. All records and reports shall be maintained at the facility and be readily available to MDEQ and to other regulatory agencies for review upon request.

Records shall always include operator and supervisor names, initials, dates, test or performance results, and remarks if applicable. Records shall also follow good and correct documentation practices According to TreatMed processes and abiding by *MDEQ Medical Waste Regulatory Program* guidelines, all records must be managed and maintained for at least three (3) years.

Universal Precautions

Universal Precautions describe a range of operational and engineering controls designed to enhance safety and eliminate or minimize employee injuries and exposure to RMW.

TreatMed employees, contractors, and visitors shall conform to Universal Precautions and exercise good working practices and safety measures that include (in no particular order or priority):

1. Supervisors shall maintain adequate working conditions, restore or overhaul any dilapidated materials, and retrofit any aged or worn equipment.
2. Supervisors shall ensure that all occupational and safety measures are observed, respected, or enforced.
3. Supervisors shall provide employees with all necessary equipment including PPE and spill control kits; it is the managers' responsibility to ensure that employees are trained to properly use all equipment and to adhere to all safety guidelines.
4. Employees shall conform to all RMW regulatory guidelines, TreatMed policies, and work practices.
5. Employees shall follow sanitary measures and ensure that the facility is maintained in clean and sanitary conditions. All contaminated equipment and working surfaces shall be decontaminated and washed instantly after being in contact with RMW.
6. Employees shall not operate any damaged or faulty equipment or devices and shall request immediate fix or replacement of any malfunctioning systems.
7. Employees shall adhere to Biosafety program and shall use proper PPE as required.
8. Under no circumstances employees may breach safety procedures or bypass equipment safety systems and interlock mechanisms.