

2. Date prepared for intake: JAN - 7 2010 AA staff initials: CHS

3. Triage review date: 1/6/2010 Triage staff initials: \_\_\_\_\_

4. Date Returned to Cases to Open/Not Going Forward/Refer Bin \_\_\_\_\_

5. SA Number: SA-INV-1022 Date: JAN - 7 2010 AA Staff initials: CHS

6. AA Staff Action: CAS-2010-0033 Date \_\_\_\_\_ AA Staff initials: \_\_\_\_\_

License Number: 278005 Type: (circle one) (RN) LN

Prior complaints: Ø Consent Agreement Eff. Date \_\_\_\_\_ → \_\_\_\_\_  
(Attach Copy of Agreement)

Allegation Summary: (please write clearly for OPP staff ITD entry)

\_\_\_\_\_  
\_\_\_\_\_

Disposition:  
1.) Open Staff Assignment:  Assign: LMM \_\_\_\_\_ <sup>IH</sup> EMP \_\_\_\_\_ MFS \_\_\_\_\_ MEM \_\_\_\_\_

Information requested: (please write clearly for OPP staff ITD entry)  
Obtain HCO Statement of deficiencies + facility  
Plan of Correction to evaluate <sup>Licensee's</sup> role + her  
response to HCO

2) Open Complaint: \_\_\_\_\_ Assign: LMM \_\_\_\_\_ EMP \_\_\_\_\_ MFS \_\_\_\_\_ MEM \_\_\_\_\_

Priority Code: \_\_\_\_\_  Duty to Report [244 CMR 9.03 (26)]

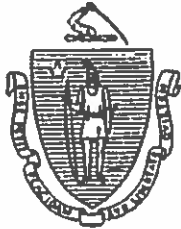
3) Inform the complainant (OPP staff to generate letter):

- The Board has no jurisdiction in this matter \_\_\_\_\_
- There is no violation of the rules and regulations \_\_\_\_\_
- The matter is being referred to another agency \_\_\_\_\_

4) No SA - No Complaint - No Letter \_\_\_\_\_

Reviewers:  
J. Pontikas \_\_\_\_\_ E. Lindberg \_\_\_\_\_ ( ) \_\_\_\_\_ ( ) \_\_\_\_\_

Acknowledgement Letter <input checked="" type="checkbox"/>	Intake Spreadsheet <input checked="" type="checkbox"/>	Warehouse Printout <input checked="" type="checkbox"/>
--	--	--



The Commonwealth of Massachusetts  
 Executive Office of Health and Human Services  
 Department of Public Health  
 Division of Health Professions Licensure  
 239 Causeway Street, Boston, MA 02114

DEVAL L. PATRICK  
GOVERNOR

TIMOTHY P. MURRAY  
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD  
SECRETARY

JOHN AUERBACH  
COMMISSIONER

Office of Public Protection

Phone: (617) 973-0865

Fax: (617) 973-0985

COMPLETED

REQUEST FOR STAFF ASSIGNMENT

BOARD Name: BOARD OF NURSING

REQUESTED BY: ELIZABETH LINDBERG DATE ASSIGNED: 1/7/10

INVESTIGATOR ASSIGNED: ICHELLE HERBU

Summary of Assignment: OBTAIN HCQ STATEMENT OF DEFICIENCIES AND FACILITY PLAN OF CORRECTION TO EVALUATE THE LICENSEE'S ROLE AND HER RESPONSE TO HCQ.

(To Be Filled Out By Admin. Staff)

Assignment Number: SA - INV - 1022

Case number: CAS-2010-0033

(To be filled out by Investigator)

Complainant Name: redact Phone #: \_\_\_\_\_

Home Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Subject of Assignment: JURENA, CHRISTIE Lic #: RN 278008

Home Address: \_\_\_\_\_ Phone #: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Business Name: \_\_\_\_\_ Lic #: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

COMPLETED  
GB

DISPOSITION: ( See Report Attached )

Investigators Signature: J. Chubb H.L.C. Date Complete: 2/3/10

Additional Information attached:  Yes  No

Sent to Board  Other Disposition \_\_\_\_\_

(To be filled out by supervising investigator)

*Close SA. No basis for a formal complaint investigation.*

Send to BD  Open Complaint [Allegation Code: \_\_\_\_\_]  Task Complete

Supervisor's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Board Action: \_\_\_\_\_

Reviewed by Board on     /    /    

Open Complaint [Allegation Code: \_\_\_\_\_]  Not Going Forward

Letter sent to complainant (see attached)  OPP Staff to send letter to complainant

Letter sent to licensee (see attached)  OPP Staff to send letter to licensee *-omit*

Additional Action Required: (please specify): \_\_\_\_\_

Board Staff Signature \_\_\_\_\_

Date \_\_\_\_\_

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

**Investigation Number : SA-INV-1022**

**Licensee : RN278008/Christie L Jurena**

**Licensee Name : Christie L Jurena**

**Investigation # : SA-INV-1022**

**Date Entered : 01/07/2010**

**Investigator : Ichelle Herbu**

**Date Assigned : 01/07/2010**

**Supervisor : Elizabeth Lindberg**

**Section 1 Licensee Information**

LICENSE NUMBER	LICENSE TYPE	D.O.B	ISSUE DATE	EXPIRATION DATE	LICENSE STATUS
RN278008	Nurse Practitioner (RN/NP)	1981	08/02/2007	07/28/2010	Current
RN278008	Registered Nurse	1981	08/02/2007	07/28/2010	Current

**Address Of Record**

**Street :** 

**City\_State\_Zipcode :** 

**Country : United States**

**Cell Phone :**

**Home Phone :**

**Fax :**

**E-Mail :**

**Current Address : **  
**(If Different)**

**Subject of Staff Assignment : (If NOT Licensee)**



**Complaint History**

\*\*\*\*\* NO OTHER COMPLAINTS RELATED TO THE LICENSEE \*\*\*\*\*

**Other Massachusetts License(s) Held**

\*\*\*\*\* NO OTHER LICENSES FOR THE LICENSEE \*\*\*\*\*

**Non-Massachusetts License(s) Held (state/jurisdiction, profession/trade, license no., status, discipline, history)**

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

**Investigation Number : SA-INV-1022      Licensee : RN278008/Christie L Jurena**

Verified in NURSYS as licensed in MA only, 02/01/10

**Current Employer Name & Address:**

Four Women Health Services(Four Women), 150 Emory St., Attleboro, MA 02703

**Supervisor Name, Title & Phone:**

Unknown

**Attorney of Record (Name, Name of Law Firm, Address, Phone):**

None

**Criminal Offender Record Information (COR) done?**       Yes       No

**Date of CORI Report: \_\_\_\_\_ Convictions?**       Yes       No

**Companion Complaints**

COMPLAINT NUMBER	COMPLAINT TYPE	COMPLAINT STATUS
None		

**Section 2 Setting of Alleged Incident/Conduct**

**Participant Type : INCIDENT LOCATION**

**Address Of Record**

**Name :** Four Women Health Services

**Street :** 150 Emory St.

**City\_State\_Zipcode :** Attleboro MA 02703

**Country :** United States

**Cell Phone :**

**Home Phone :** 5082227555

**Fax :**

**E-Mail :**

**Incident Location Details : (If Different)**

**Contact Person Name & Title:**

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

**Investigation Number : SA-INV-1022      Licensee : RN278008/Christie L Jurena**

**Address & Phone:**

\_\_\_\_\_

**Name & Address of Employer if different from above:**

\_\_\_\_\_

**Contact Person & Title:**

\_\_\_\_\_

**Phone:**

\_\_\_\_\_

**Section 3A Persons Interviewed**

Name & Title Of Person Interviewed	Date	Type (Phone, In-Person)	Address & Phone
redacted, Director, Community Sanitation Program	01/25/10	Phone	<b>Address:</b> 250 Washington Street, Boston, MA 02108 <b>Phone:</b> 617-624-5757

**Section 3B Persons Unavailable For Or Declining Interview**

Name/Title & Relationship To The Complaint	Date	Address & Phone	Reason (Decline, Not Able To Contact, Other)
None			

**Section 3C Other Agencies/Entities Involved In Or Investigating The Alleged Conduct**

Agency	Contact Name/Title	Address & Phone
The Commonwealth of	Steven Hughes, Director,	<b>Address:</b> 250 Washington

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

Investigation Number : SA-INV-1022

Licensee : RN278008/Christie L Jurena

Massachusetts, Executive Office of Health and Human Services, Department of Public Health, Bureau of Environmental Health, Community Sanitation Program(CSP)	Community Sanitation Program	Street, Boston, MA 02108 Phone: 617-624-5757

**Section 4 Investigation Summary**

**Complaint Allegation(s):**

Based on information received by the Massachusetts Board of Registration in Nursing (Board) an inquiry into concerns about the Licensee's nursing practice has been initiated. Specifically, the information alleges that on or about November 4, 2009, while Licensee was working as a registered nurse and administrator at Four Women Health Services, Attleboro, MA, she did not properly dispose and manage the medical or biological waste generated at the facility. Hence, she comprised the safety of the public and her co-workers.

**Documentation, including interviews & written witness statements, that supports allegation(s):**

***A review of the documentation submitted by the Complainant shows:  
Signed and Dated 12/11/09, CSP Investigation Report, the Director of CSP states:***

1. On November 4, 2009, CSP and the Attleboro Health Department conducted a compliance inspection at Four Women. The inspection was conducted in response to an alleged violation of 105 CMR 480.200; that is, illegal disposal of medical and biological waste as a solid municipal waste.
2. **Findings:**
  - CSP determined that Four Women had numerous deficiencies in its medical or biological waste management, and was not in compliance for the following requirements of 105 CMR 480.000:
    - The area used for medical waste storage lacked appropriate signage indicating the presence of regulated medical or biological waste.
    - The area used for medical waste storage lacked appropriate security to prevent unauthorized access.
    - The storage area does not allow clear separation of regulated medical waste(red bags/sharps/pathological waste).
    - Required written procedures were not maintained for the poor management of medical or biological waste.
    - Required medical waste record-keeping log was not maintained.
    - Required written contingency plan for spills and accidents was not maintained.
3. **Corrective Actions:** CSP required 8 corrective actions for the listed deficiencies, and

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

**Investigation Number : SA-INV-1022      Licensee : RN278008/Christie L Jurena**

expected Four Women to respond in writing by 01/15/10.

**Documentation, including interviews and written witness statements, that does not support or that refutes the allegations:**

01/25/10, Board Investigator's telephone interview, the Director of CSP states:

- CSP inspected Four Women, and Licensee was the point of contact for the facility. She recently submitted a plan of corrective actions on behalf of the facility.

**Other Information/Evidence that supports the Allegations:**

**A review of the documents submitted to CSP from Four Women shows:**

1. *Signed and dated 01/12/10, Copy of a Letter to CSP from the Facility, Licensee states:*
  - Four Women has taken the issues seriously, and has addressed each corrective action in details. The minimum requirement had been met, and the facility continues to strive to exceed those requirements.
2. *Four Women's Table of Summary for each Corrective Action Required and Action Taken:*

<b>Corrective Action Required</b>	<b>Action taken</b>	<b>Effective</b>
A. Four Women must evaluate and redesign all existing policies for the handling of medical and biological waste.	Policies have been reviewed amended or created to ensure compliance	12/2009
B. The space utilized for handling and storage of medical or biological waste shall be reconfigured to improve the handing and clear separation of the red bags/boxes, sharps and pathological waste. Waste being sent off-site for treatment must be properly stored in a designated and marked area that only allows authorized access. The area cannot be used for multipurpose.	A closet was reconstructed within the clinic for storage of medical and biological waste. Red bags, sharps containers, and pathological waste are clearly marked. The space is locked and only allows authorized access.	12/2009
C. Documentation must be provided to CSP that ventilation discharges directly to the exterior of the buildings away from any fresh air intakes.	Four Women has contracted with a HVAC provider, Environmental Systems, Inc., to upgrade the biohazard storage closet in order to meet appropriate ventilation requirements.	01/31/10
D. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded	Policies for waste packaging, storage and disposal have been updated to include medical waste record keeping.	12/09



**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

**Investigation Number : SA-INV-1022**

**Licensee : RN278008/Christie L Jurena**

in the required medical waste record-keeping log.		
E. Four Women must provide CSP documentation including medical waste record-keeping logs and shipping papers/tracking forms for all waste sent off-site for treatment since August 1, 2008.	Attached are all shipping papers and tracking forms for waste sent off-site for treatment since August 1, 2008. Also attached is a copy of the record-keeping log.	12/09
F. Written policies and procedures for the handling, storage and shipment of all medical or biological waste must be established. A copy must be provided to CSP.	Attached is the updated policy	12/09
G. Four women must provide specific plans and documentation demonstrating fulfillment of training for all current and future staff involved in medical and biological waste management.	All existing staff was retrained, and all new employees will be required to read the Infection Control Policy Manual. Training will be documented in the employee file and the Waste Record Keeping log.	12/09 and ongoing

3. Dated 01/06/10, Copy of a Letter from Environmental Systems, Inc to Four Women, the sales engineer states:
  - o a proposal for modifying the Bio-hazard storage closet to ensure the proper ventilation requirements.
4. Dated 11/18/09, Copy of Stericycle Service Agreement for removal and disposal of Waste:
  - o Effective Date 12/01/10
5. Dated 02/13/09 to 12/22/09, Copy of Four Women's MA Department of Public Health Medical or Biological Waste Record-Keeping Log Off-Site Treatment
6. Dated 08/07/09 to 12/23/09, Copy of Tracking Forms for Waste sent Off-Site for Treatment
7. Dated 01/10, Copy of Four Women's Employee Training Agreement for Management of Biological Waste
8. Undated, Four Women's Policy and Procedure for Waste Disposal and Hazard Communications

**Licensee's response:**

Board did not request a response from Licensee

**Information/Evidence requested and not received:**

**MDPH Division Of Health Professions Licensure  
Board of Registration in Nursing  
STAFF ASSIGNMENT REPORT**

Investigation Number : SA-INV-1022

Licensee : RN278008/Christle L Jurena

**Investigator's Determination of Findings:**

The documentation in the file shows that Licensee was the point of contact for Four Women. During an inspection at the facility, CSP found numerous deficiencies related to the facility's disposal and management of medical or biological waste, and required the facility to complete 8 corrective actions. As requested by CSP, Licensee responded, and submitted documents of actions taken by the facility to address each corrective action.

**Relevant Law(s) and Regulation(s):**

1.	
2.	
3.	

Investigator Signature: *Michelle Hill*

Date: *02/03/10*

Supervisor Signature: *E Lindberg*

Date: *3/3/10*

**Section 5 Board Action on Complaint**

DPH Date Rec'd / stamped  
**RECEIVED**

**NURSING  
COMPLAINT  
FORM**

**DEPARTMENT OF PUBLIC HEALTH  
DIVISION OF HEALTH PROFESSIONS LICENSURE  
OFFICE OF PUBLIC PROTECTION**  
TEL (617) 973-0865 FAX (617) 973-0985 TTY (617) 973-0895  
<http://www.mass.gov/dph/boards>

**DEC 29 2009**  
OFF. PUBLIC PROTECTI

**DPH USE ONLY:**

Entered into Database (date) \_\_\_\_/\_\_\_\_/\_\_\_\_ Complaint # \_\_\_\_\_ Initials \_\_\_\_\_

Please complete this form as fully as possible. Please TYPE or WRITE LEGIBLY in ink.

**COMPLAINANT**

Mr.  
 Mrs.  
 Ms. \_\_\_\_\_

_____	_____	_____	_____	_____
Your Last Name	Your First Name	Patient's Name (if different)	Patient's Age	
Your Business Name: _____ (if applicable)				
Business Address: _____				
_____	_____	_____	_____	_____
Street	City	State	Zip	
Complainant Address: _____				
_____	_____	_____	_____	_____
Street	City	State	Zip	
Patient's Address (if different): _____				
_____	_____	_____	_____	_____
Street	City	State	Zip	
_____	_____	_____	_____	_____
Your Primary Phone number: ( )	Your Secondary Phone number: ( )	Your Email:		

**LICENSEE**

REGISTERED NURSE     LICENSED PRACTICAL NURSE     ADVANCED PRACTICE NURSE

_____	_____	_____
Licensee's Last Name	Licensee's First Name	Lic # (if known)
Business Name: FOUR WOMEN HEALTH SERVICES _____		
Phone #: 508) 222-7555		
Business Address: 150 Emory St., Attleboro, MA 02703 _____		
_____	_____	_____
Street	City	State Zip

**COMPLAINT DESCRIPTION**

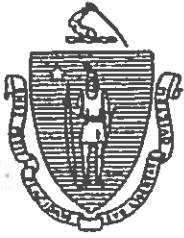
DATE(S) OF INCIDENT(S): Nov. 4, 2009

DETAILS OF COMPLAINT: Clearly describe the incident(s) leading up to your complaint. If applicable, attach copies of documents such as: witness statements, medical records, copies of prescriptions, photographs etc. that support your statements. PLEASE SEND COPIES; originals will not be returned to you. Attach extra paper as needed to complete this section.

Nurse Christie Jurena, as administrator and the Four Women Health Services, has been derelict in her duty to fulfill the legal requirements with following 105 CMR 480.000. As listed in the DPH letter of Dec. 12, 2009 to Christie Jurena it states there was a lack of appropriate signage indicating biological waste. Also the medical waste storage lacked appropriate security. Also the currently configured storage area does not allow clear separation of regulated medical waste. Also required written procedures wer not maintained for the proper management of medical or biological waste. Also waste record-keeping log was NOT maintained. Also a required written contingency plan for spills and accidents was not maintained. All these findings violated 105 CMR 480.100C(1)(2)(4) and 105 CMR 480.500(A)and (I) and (B) and (C)

**Legal Representative, or**  
(attach documentation)

**Complainant**



DEVAL L. PATRICK  
GOVERNOR

TIMOTHY P. MURRAY  
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD  
SECRETARY

JOHN AUERBACH  
COMMISSIONER

The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Environmental Health  
Community Sanitation Program  
250 Washington Street, Boston, MA 02108-4619  
Telephone (617) 624-5757  
Facsimile (617) 624-5777

DEC 16 2009

Christie L. Jurena, MPH, RN, MS, WHNP-BC  
Administrator  
Four Women Health Services  
150 Emory Street  
Attleboro, MA 02703

December 12, 2009

Re: Complaint investigation re: compliance with requirements for medical waste management

Dear Ms. Jurena,

On November 4, 2009, the Department of Public Health's Community Sanitation Program (CSP) and the Attleboro Health Department conducted a compliance inspection at Four Women Health Services located at 150 Emory Street, Attleboro, MA. This inspection was conducted in accordance with M.G.L. c. 111, §127A, and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), in response to an alleged violation of 105 CMR 480.200 – illegal disposal of medical or biological waste as solid municipal waste. In addition, the complaint and this investigation report have been forwarded to the Department's Division of Health Care Quality which is responsible for investigation of complaints involving clinics licensed pursuant to 105 CMR 140.000.

#### FINDINGS

Based on observations made during the on-site inspection, the CSP determined that Four Women Health Services had numerous deficiencies in its medical or biological waste management and was not in compliance with the following requirements of 105 CMR 480.000:

- The area used for medical waste storage lacked appropriate signage indicating the presence of regulated medical or biological waste. A single loose red bag of unidentified medical or biological waste was present (but not labeled for shipment) on the floor of a multi-purpose storage/hot water heater room without clear signage [105 CMR 480.100(C)(1)].
- The area used for medical waste storage lacked appropriate security to prevent unauthorized access [105 CMR 480.100(C)(2)].

- As currently configured the storage area does not allow clear separation of regulated medical waste (red bags/sharps/pathological waste) [105 CMR 480.100(C)(4)].
- Required written procedures were not maintained for the proper management of medical or biological waste [105 CMR 480.500(A) and 105 CMR 480.500(I)].
- Required medical waste record-keeping log was not maintained [105 CMR 480.500(B) and 105 CMR 480.500(I)].
- Required written contingency plan for spills and accidents was not maintained [105 CMR 480.500(C) and 105 CMR 480.500(I)].

## **CORRECTIVE ACTIONS**

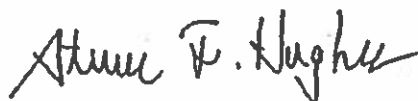
Based on the November 4, 2009 inspection, the Department requires the following corrective actions:

1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.
2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.
3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.
4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.
5. Four Women Health Services must provide to the Department documentation including medical waste record-keeping logs and shipping papers / tracking forms for all waste sent off-site for treatment since August 1, 2008.
6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.
7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.

Four Women Health Services must provide a response in writing regarding these corrective actions to the Community Sanitation Program by January 15, 2010. Please be advised that pursuant to 105 CMR 480.600(C), this letter constitutes notice to Four Women Health Services of the nature of these current violations and that any additional violations of 105 CMR 480.000 may result in legal action.

Please feel free to contact me at (617) 624-5757 if you have further questions regarding this matter.

Sincerely,



Steven F. Hughes  
Director, Community Sanitation Program

CC:

Suzanne K. Condon, Associate Commissioner, Director, BEH  
James Ballin, Deputy General Counsel, DPH  
Lisa Noling Snellings, Deputy General Counsel, DPH  
Lillian Jette, DHCQ  
Sherman Lohnes, DHCQ  
James P. Mooney, Health Director, Attleboro

**F O U R  
W O M E N**

Health Services

January 12, 2010

Steven F. Hughes  
Director, Community Sanitation Program  
DPH, Bureau of Environmental Health  
250 Washington Street  
Boston, MA 02108-4619

Dear Mr. Hughes,

I am writing in response to your letter dated December 12, 2009 (Re: Complaint investigation re: compliance with requirements for medical waste management). Based on your inspection, there were a number of corrective actions that were required by your Department. Please see the attached document addressing each corrective action. Four Women has taken this issue seriously and addressed each requirement in detail. The minimum requirement has been met, and we continue to strive to exceed those requirements. Please contact me if you have any questions regarding this response, or the accompanying documents.

Sincerely



Christie Jurena, MPH, RN, MS, WHNP-BC  
Nurse Administrator  
Four Women Health Services

Cc: Marcus Gordon, MD, Medical Director, Four Women Health Services



Corrective Action required	Action taken	Effective date
1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.	Policies have been reviewed, amended or created to ensure compliance with 105 CMR 480.000. A copy of pertinent policies and procedures is attached.	12/2009
2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.	Contracted builders reconstructed a closet within the clinic for storage of medical and biological waste. The closet is large enough to accommodate the maximum amount of potential stored waste pending pickup. There is clear separation of red bags, sharps containers, and pathological waste. The space is locked and only allows authorized access. Additionally, appropriate signage has been affixed to the door of the closet. A weather strip has been added in order to prevent odors from escaping.	12/2009
3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.	We have contracted with our HVAC provider, Environmental Systems, Inc. to upgrade our biohazard storage closet in order to meet appropriate ASHRAE and DPH guidelines. The proposal is attached and outlines the modification to discharge the air in the storage closet directly to the outdoors. The vent and ductwork is already in place, it only needs to be connected. This project will be completed as soon as possible.	1/31/2010
4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.	Policies for waste packaging, storage and disposal have been updated to include medical waste record keeping. Copies of the medical waste record-keeping log have been attached.	12/2009
5. Four Women Health Services must provide to the	Attached are all shipping papers and tracking forms for	12/2009

Department documentation including medical waste record-keeping logs and shipping papers/tracking forms for all waste sent off-site for treatment since August 1, 2008.	waste sent off-site for treatment since August 1, 2008. Also attached is a copy of the record-keeping log.	
6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.	Attached is the updated policy regarding the storage and shipment of biological waste. Attention is made to the clear separation of red bags and sharps, and pathological waste.	12/2009
7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.	A staff in-service was performed in order to train existing staff on the handling of regulated waste. All new employees responsible for handling regulated waste will be required to read the Infection Control policy manual, which includes all policies related to regulated waste, and training will be documented in the employee file and the Waste Record Keeping log.	12/2009 and ongoing



Mechanical Contractors and Engineers

6 Howard Ireland Drive  
Attleboro, MA 02703-4612  
508 226-6006 | 508-222-1344  
www.envsys.net

January 6, 2010

Four Women Health Services  
150 Emory Street  
Attleboro, Ma. 02703

Attn: Christie Jurena

Re: Bio-hazard closet exhaust

Christie,

We are pleased to offer the following proposal for HVAC upgrades at the above referenced facility.

This modification will insure that the proposed Bio-hazard storage closet will be exhausted directly to the outdoors and that the termination point for this exhaust will meet the minimum distance criteria in relationship to any fresh air intakes or operable windows.

Bio-hazard exhaust

We propose to replace the existing ceiling grille and run new duct to an adjacent exhaust system. The existing exhaust system is capable of handling the modest increase in exhaust air as the closet totals only 30 cubic feet. At an exhaust rate of 40 CFM the air change rate would approach 80 air changes per hour.

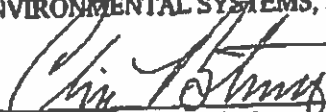
The cost for installation of the exhaust system components as outlined above would be \$585.00.

The above proposal does not include a new ceiling tile if required.

Thank you for the opportunity to assist you with this project. If you should have any questions, please do not hesitate to call.

Yours truly,

ENVIRONMENTAL SYSTEMS, INC.

  
Chris Bradstreet, Sales Engineer



Stericycle

Account/ Site # \_\_\_\_\_

STERI-SAFE<sup>SM</sup> SERVICE AGREEMENT

Service Address

Billing Address (If Different)

Name: Four Women Health Services
Address 1: 150 Emory Street
Address 2:
City/State/Zip: Andover, MA 02703
E-Mail: redact
Phone: (508) 222-7555 ext. Fax: (508) 226-2218
Contact: Christie Jurena Title: Manager

Name: Same
Address 1:
Address 2:
City/State/Zip:
E-Mail: same
Phone: ( ) - - ext. Fax: ( ) - -
Contact: Title:

The parties agree as follows:

- 1 The Effective date of this agreement is 12/01/2009
2 Stericycle shall remove and dispose of Customer's Regulated Medical Waste (Hazardous Waste as applicable) subject to the terms and conditions set forth below
3 Stericycle will provide additional compliance services for the prices applicable to the service program level Customer has selected below

Services to be Provided

Form containing STERI-SAFE w/ RMW details, Special Waste Services, and Total Monthly Fee: \$ 243.50

By signing below I acknowledge that I am the Customer's authorized officer or agent and that I have the authority to bind Customer to this Agreement. Customer agrees to be bound by the terms and conditions that appear on following pages hereof and comply with Stericycle's Waste Acceptance Policy, both of which are integral parts of this Agreement.

Stericycle reserves the right to deal solely with the Customer and not with any third party agents of the customer for all purposes relating to this Agreement. Customer represents and warrants to Stericycle that it is the medical waste generator and is acting for its own account and not through a broker or agent. Stericycle shall be entitled to terminate this agreement and seek all available legal remedies, including but not limited to liquidated damages, in the amount set forth herein for Customer's breach of this representation and warranty.

CUSTOMER: X PLEASE PRINT: Title Date:

STERICYCLE: X PLEASE PRINT: Brent Mancuso Title HCR Date: 11/18/09

STERICYCLE USE ONLY section containing agreement details, tax exemption, purchase order, and routing information.

Stericycle, Inc. • www.stericycle.com • 2333 Waukegan Rd Ste 300 Danvers, MA 01923 • P (847) 943-6722 ext. • F (800) 349-0626
The offer will expire on \_\_\_\_\_

Updated 7-1-09

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**  
**Medical or Biological Waste Record-Keeping Log**  
**OFF-SITE TREATMENT**

Facility Name & Address: Four Women Health Services - 150 Emory St. Attleboro, MA 02203

In accordance with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-keeping log with the following information: the exact date of shipment; the total number of containers; the type of waste; the total combined weight or volume; the name of the transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of corresponding forms for each shipment; and the printed name and signature of the person responsible for shipping the waste.

Date	Containers	Type	Weight or Volume	Transporter	ID# (if applicable)	Please Check:		Printed
						Shipping Paper	Tracking Form	Signature
2/13/09	2	Medium Corrugated	8	Stericycle	MDW5000XPS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
3/13/09	3	Medium Corrugated	12	Stericycle	MDW800220	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
4/10/09	3	Medium Corrugated	12	Stericycle	MDW5007960	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
5/19/09	2	Medium Corrugated	8	Stericycle	MDW500786N	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
6/15/09	2	Medium Corrugated	8	Stericycle	MDW500724K	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
6/26/09	3	Medium Corrugated	12	Stericycle	MDW500722G	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Christie Juena Christie Juena
						<input type="checkbox"/>	<input type="checkbox"/>	
						<input type="checkbox"/>	<input type="checkbox"/>	

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**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH  
 Medical or Biological Waste Record-Keeping Log  
 OFF-SITE TREATMENT**

Facility Name & Address: Four Women Health Services - 156 Emory St. Attleboro, MA 01703

In accordance with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-keep with the following information: the exact date of shipment; the total number of containers; the type of waste; the total combined weight or volume; the transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of corresponding forms for each shipment; and the printed name and signature of the person responsible for shipping the waste.

Date	Containers	Type	Weight or Volume	Transporter	ID# (if applicable)	Please Check:		Printed I Signal
						Shipping Paper	Tracking Form	
7/9/08	3	Medium corrugated	12	Stericycle	MDWS0006M	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
8/6/08	4	Medium corrugated	16	Stericycle	MDWS0004H6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
8/24/08	2	Medium corrugated	8	Stericycle	MDWS0009L	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
9/24/08	2	Medium corrugated	8	Stericycle	MDWS0006AL	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	SB
10/23/08	2	Medium corrugated	8	Stericycle	MDWS0006KM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	SB
11/24/08	2	Medium corrugated	8	Stericycle	MDWS0006ZI	<input type="checkbox"/>	<input checked="" type="checkbox"/>	SB
12/19/08	2	Medium corrugated	8	Stericycle	MDWS0006H8	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
1/16/09	2	Medium corrugated	8	Stericycle	MDWS0006D8	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	SB

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**  
**Medical or Biological Waste Record-Keeping Log**  
**OFF-SITE TREATMENT**

Facility Name & Address: Four Women Health Services - 100 Emory Street Attleboro, MA 02703

In accordance with M.G.L. c. 111 § 3, 5, and 127A and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-keep with the following information: the exact date of shipment; the total number of containers; the type of waste; the total combined weight or volume; the name of the transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of corresponding forms for each shipment; and the printed name and signature of the person responsible for shipping the waste.

Date	Containers	Type	Weight or Volume	Transporter	ID# (if applicable)	Please Check:		Printed & Signed
						Shipping Paper	Tracking Form	
8/1/09	4	Medium Corrugated	16	Stericycle	MDWS080LP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>
8/28/09	1	Medium Corrugated	4	Stericycle	MDWS0856N	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>
9/16/09	1	Medium Corrugated	5	Stericycle	MDWS089KA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Christie Jurena <i>Christie Jurena</i>
9/25/09	3	Medium Corrugated	12	Stericycle	MDWS088XZ	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>
10/21/09	3	Medium Corrugated	12	Stericycle	MDWS090AZT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>
11/24/09	1	Medium Corrugated	4	Stericycle	MDWS090BT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>
12/22/09	3	Medium Corrugated	12	Stericycle	MDWS090BF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Kara Brooks <i>Kara Brooks</i>

**Four Women Health Services  
Management of Biological Waste Training Agreement**

**Employee name:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

***Initial***

\_\_\_\_\_ I have read and understand the information contained in the Infection Control Manual

\_\_\_\_\_ I have been given the opportunity to ask questions regarding the management of biological waste and have them answered

\_\_\_\_\_ I have been trained by a proficient staff member in the management of biological waste.

\_\_\_\_\_ I am confident in my ability to segregate, handle and manage medical or biological waste.

\_\_\_\_\_  
Employee signature

\_\_\_\_\_  
Supervisor signature



1. Generator's Name, Address and Telephone Number

ATTN: *For Women Health Services*  
*150 Emory St.*  
*Attleboro, MA 02703-2439*  
*Phone: 222-7515*



CUSTOMER NUMBER - <i>8151902-001</i>		GENERATOR'S REGISTRATION #	
2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	TB01 - 30 Gal Reusable (4.0 cu ft)		Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WW40 - Medium Corrugated (4.0 cu ft)	<i>35</i>	<i>1220</i> Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WW45 - Medium Corrugated (4.5 cu ft)		Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WW70 - Large Corrugated (7.0 cu ft)		Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	KRBX - Large Corrugated (4.3 cu ft)		Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	ST75 - 48 Gal Reusable (7.5 cu ft)		Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	<i>WPSO 112M 4.5 CU FT</i> <del>BP18 - Large Patch/Bags Chemo - Incinerate only (3.5 cu ft)</del>	<i>2</i>	<i>8</i> Cu l
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II			Cu l
			Cu l
		<b>TOTALS ▶</b>	<i>5</i> <i>20</i> Cu l

GENERATOR

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

Printed/Typed Name *Karla Brooks* Signature *Karla Brooks* Date *12/22/09*

4. TRANSPORTER 1 ADDRESS: **STERICYCLE, INC.**  
20161 N. Keith Drive  
Lake Forest, IL 60045  
Phone # (800) 633-9278  
Applicable Permit Numbers:  
CT-SHW-005 NY-DECIL-033  
MB-BWT-033 RI-MW-TRAN-260  
NJ-DEP-19713 TNH-0210

This is a Through Shipment

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name *John Doe* Signature *John Doe* Date *12-22-09*

PRIMARY TRANSPORTER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 2 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 3 / INTERMEDIATE HANDLER

7. DISCREPANCY INDICATION  
*2 WP Y.O sent to Haw River OOST&P*

<input checked="" type="checkbox"/> 7A. Designated Facility: STERICYCLE, INC 369 PARK EAST DRIVE WOONSOCKET, RI 02895 (401) 769-3600 Permit# RI-053	<input checked="" type="checkbox"/> 7B. Alternate Facility: STERICYCLE, INC 1165 PORTER AVENUE HAW RIVER, NC 27258 (252) 578-6900 Permit# 01-02-1	<input type="checkbox"/> 7C. Alternate Facility: STERICYCLE, INC 3472 PROGRESS DRIVE DUNKIRK, NY 14048 (716) 366-4444 Permit# 9-0664-00019/00012	<input type="checkbox"/> 7D. Alternate Facility:
--	--	---	--

TREATMENT FACILITY

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name *Kim Burr* Signature *Kim Burr* Date *12-23-09*

1. Generator's Name, Address and Telephone Number

ATTN: Christie Jurena  
Four Women Health Services  
150 Emory St  
Attleboro, MA 02703-2439  
(508) 222-7555



12/18/2009

CUSTOMER NUMBER 8151902-001 GENERATOR'S REGISTRATION #

GENERATOR

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	7B01 - 30 Gal Reusable (4.0 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	9T75 - 48 Gal Reusable (7.5 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW40 - Medium Corrugated (4.0 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW45 - Medium Corrugated (4.5 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW70 - Large Corrugated (7.0 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG I	WB Bath Corrugated Incinerate Only ( cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WC Chem Corrugated Incinerate Only ( cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft
		<b>TOTALS ▶</b>	Cu Ft

3. Generator's Certification: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Printed/Typed Name \_\_\_\_\_ Signature \_\_\_\_\_ Date 12-18-09

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS: STERICYCLE, INC.  
28161 N. Keith Drive  
Lake Forest, IL 60045  
TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.  
Print/Type Name David Fleck Signature Paul Flanagan Date 12-18-09

Phone #: (800) 633-9278  
Applicable Permit Numbers:  
CT-BMW-005 NY-DECIL-033  
ME-BWT-033 RI-HW-TRAN-260  
NJ-DEP-19713 TNH-0210

This is a Through Shipment

INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:  
INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.  
Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Phone #: \_\_\_\_\_  
Applicable Permit Numbers \_\_\_\_\_

INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:  
INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.  
Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Phone #: ( ) - \_\_\_\_\_  
Applicable Permit Numbers \_\_\_\_\_

7. DISCREPANCY INDICATION  
Box 4 s/p Blank.

<input type="checkbox"/> 7A. Designated Facility: STERICYCLE, INC 369 PARK EAST DRIVE WINDSORCKET, RI 02895 (401) 789-5600 Permit# RI-053	<input type="checkbox"/> 7B. Alternate Facility: STERICYCLE, INC 1163 PORTER AVENUE HAW RIVER, NC 27258 (336) 578-6600 Permit# 01-02-1	<input type="checkbox"/> 7C. Alternate Facility: STERICYCLE, INC 2472 PROGRESS DRIVE DUNKIRK, NY 14048 (716) 368-4444 Permit# 9-0664-00019/00012	<input type="checkbox"/> 7D. Alternate Facility:
--	---	---	--

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

000169

1. Generator's Name, Address and Telephone Number

ATTN: Stephanie



CUSTOMER NUMBER

GENERATOR'S REGISTRATION #

2A. DESCRIPTION OF WASTE

2B.

CONTAINER TYPE

2C. NO. OF CONTAINERS

2D

VOLUME

2A. DESCRIPTION OF WASTE	2B.	CONTAINER TYPE	2C. NO. OF CONTAINERS	2D	VOLUME
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II			1	4	Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II					Cu l

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

TOTALS ▶ 1 4 Cu l

Print/Typed Name Kara Brooks Signature Kara Brooks Date 11/20/09

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS:

Phone #  
Applicable Permit Numbers:

STERICYCLE, INC.  
2500 N. Keith Drive  
St. Louis, MO 63045

This is a Through Shipment

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above

Print/Type Name Robert Cantagliano Signature Robert Cantagliano Date 11/20/09

TRANSPORTER 2 / INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

Phone #  
Applicable Permit Numbers

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 3 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

Phone #  
Applicable Permit Numbers

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

7. DISCREPANCY INDICATION

TREATMENT FACILITY

<input checked="" type="checkbox"/> 8A. Designated Facility:	<input type="checkbox"/> 8B. Alternate Facility:	<input type="checkbox"/> 8C. Alternate Facility:	<input type="checkbox"/> 8D. Alternate Facility:
--	--	--	--

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name Kim Burr Signature Kim Burr Date 11/20/09

1. Generator's Name, Address and Telephone Number



ATTN:  
Four Women Health Serv.  
150 Emory St  
Attleboro MA, 01703-2439  
(508) 222-7555

10/23/07

CUSTOMER NUMBER 8151902-001

GENERATOR'S REGISTRATION #

GENERATOR

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	TB01 - 30 Gal Reusable (8.0 cu ft)	3	12
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW40 - Medium Corrugated (4.0 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW45 - Medium Corrugated (4.5 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW70 - Large Corrugated (7.0 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	KR8X - Large Corrugated (9.3 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	ST75 - 48 Gal Reusable (7.5 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	BP16 - Large Path/BC16 Chemc - Incinerate Only (4.5 cu ft)		
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			
<b>TOTALS</b>		<b>3</b>	<b>12</b>

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

X Printed Name Kara Brooks Signature Kara Brooks Date 10/23/07

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS:

STERICYCLE, INC.  
28161 N. Keith Drive  
Lake Forest, IL 60045

This is a Through Shipment

CT-BMW-005 NY-DECIL-033  
ME-BWT-033 RI-MW-TRAN-260  
NJ-DEP-19713 TNH-0210

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name Michael [Signature] Signature [Signature] Date 10/23/07

TRANSPORTER 2 / INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 3 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TREATMENT FACILITY

7. DISCREPANCY INDICATION

<input checked="" type="checkbox"/> 6A. Designated Facility:	<input type="checkbox"/> 6B. Alternate Facility:	<input type="checkbox"/> 6C. Alternate Facility:	<input type="checkbox"/> 6D. Alternate Facility:
STERICYCLE, INC 369 PARK EAST DRIVE WOONSOCKET, RI 02895 (401) 789-5800 Permit# RI-053	STERICYCLE, INC 1163 PORTER AVENUE HAW RIVER, NC 27259 (336) 578-8900 Permit# 01-02-1	STERICYCLE, INC 3472 PROGRESS DRIVE DUNKIRK, NY 14048 (716) 366-4444 Permit# 9-0664-00019/00012	

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name Kim Burr Signature Kim Burr Date 10/23/07

000342

1. Generator's Name, Address and Telephone Number

ATTN: Stephenie  
Four Women Health Services  
150 Emory St  
Attleboro, MA 02703-2439  
(508) 222-7555



9/25/2009

CUSTOMER NUMBER 8151902-001

GENERATOR'S REGISTRATION #

GENERATOR

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE nos. 6.2, UN 3291, PG II	T801 - 30 Gal Reusable (8.0 cu ft)		Cu F
REGULATED MEDICAL WASTE nos. 6.2, UN 3291, PG II	WW10 - Medium Corrugated (4.0 cu ft)	3	12 Cu F
REGULATED MEDICAL WASTE nos. 6.2, UN 3291, PG II	WW45 - Medium Corrugated (4.5 cu ft)		Cu F
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WW70 - Large Corrugated (7.0 cu ft)		Cu F
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	KRBX - Large Corrugated (8.3 cu ft)		Cu F
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	ST75 - 18 Gal Reusable (7.5 cu ft)		Cu F
REGULATED MEDICAL WASTE nos. 6.2, UN 3291, PG II	BP18 - Large Path/BP36 Chemo - Incinerate Only (8.5 cu ft)		Cu F
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II			Cu F
			Cu F
		<b>TOTALS ▶</b>	3 12 Cu F

3. Generator's Certification: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

X Printed/Typed Name KARA BROOKS Signature Kim Brooks Date 9/25/09

Phone #: (800) 633-5278

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS:  
STERICYCLE, INC.  
28161 N. Keith Drive  
Lake Forest, IL 60045

This is a Through Shipment

Applicable Permit Numbers  
CT-BMW-005 NY-DECIL-033  
ME-BWT-033 RI-MW-TRAN-260  
NJ-DEP-19713 TNH-0210

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name Deret Peloguin Signature Deret Peloguin Date 9/25/09

Phone # \_\_\_\_\_  
Applicable Permit Numbers \_\_\_\_\_

TRANSPORTER 2 / INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 3 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Phone # ( ) - \_\_\_\_\_  
Applicable Permit Numbers \_\_\_\_\_

7. DISCREPANCY INDICATION

TREATMENT FACILITY

<input checked="" type="checkbox"/> 7A. Designated Facility: STERICYCLE, INC 389 PARK EAST DRIVE WOONSOCKET, RI 02895 (401) 769-5800 Permit# RI-053	<input type="checkbox"/> 7B. Alternate Facility: STERICYCLE, INC 1168 PORTER AVENUE HAW RIVER, NC 27568 (336) 578-6900 Permit# 01-02-1	<input type="checkbox"/> 7C. Alternate Facility: STERICYCLE, INC 3472 PROGRESS DRIVE DUNKIRK, NY 14048 (716) 365-4444 Permit# 9-0654-00019/00012	<input type="checkbox"/> 7D. Alternate Facility:
--	---	---	--

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name Kim Burr Signature Kim Burr Date 9-27-09



IN CASE OF EMERGENCY CONTACT: CHEMTREC 1-800-234-0051  
 Hours: 24/7

STANDARD MANIFEST 001-10-06-310  
 MDW300913

1. Generator's Name, Address and Telephone Number

ATW Staphoria  
 Fruit Women Health Services  
 170 Emily St.  
 Attleboro, MA 01903-2099  
 (508) 212-7555



CUSTOMER NUMBER 8151902-001

GENERATOR'S REGISTRATION #

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	TR01 - 20 gal Reusable (11.5 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM40 - Medium Concentrated (4.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM45 - Medium Concentrated (4.0 cu ft)	1	3 Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM70 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM80 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM85 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM90 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM95 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM98 - Large Concentrated (3.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, nos. 6.2, UN 3291, PG II	WM99 - Large Concentrated (3.0 cu ft)		Cu Ft.
		<b>TOTALS ▶</b>	1.5 Cu Ft.

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

X Printed/Typed Name: Christie Jurena Signature: Christie Jurena Date: 9/16/09

4. TRANSPORTER 1 ADDRESS:

STERICYCLE, INC.  
 18161 N. Keith Drive  
 Lake Forest, IL 60045

This is a Tough Shipment!

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name: Michael Smith Signature: [Signature] Date: 16 Sept 09

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

7. DISCREPANCY INDICATION

<input checked="" type="checkbox"/> 7A. Designated Facility: STERICYCLE INC 18161 N. KEITH DRIVE LAKE FOREST, IL 60045 (708) 455-5555 Permit: RI-023	<input type="checkbox"/> 7B. Alternate Facility: STERICYCLE INC 18161 N. KEITH DRIVE LAKE FOREST, IL 60045 (708) 455-5555 Permit: RI-023	<input type="checkbox"/> 7C. Alternate Facility: STERICYCLE INC 1472 PROGRESS DRIVE SUNNYSIDE, NY 10969 (914) 355-4444 Permit: 9-0264-0001903012	<input type="checkbox"/> 7D. Alternate Facility:
---	---	---	--

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name: Kim Burr Signature: Kim Burr Date: 9-17-09

000203

1. Generator's Name, Address and Telephone Number

ATTN: Stephanie  
Four Women Health Services  
150 Emory St  
Attleboro, MA 02703-2439  
(508) 222-7555



8/28/2009

CUSTOMER NUMBER **8151902-001**

GENERATOR'S REGISTRATION #

GENERATOR

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	TB01 - 30 Gal Reusable (6.0 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	WM40 - Medium Corrugated (4.0 cu ft)	1	4 Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	WM45 - Medium Corrugated (4.5 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	WM70 - Large Corrugated (7.0 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	KRX - Large Corrugated (8.3 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	ST75 - 48 Gal Reusable (7.5 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II	BP18 - Large Path/BC36 Chemo - Incinerate Only (8.5 cu ft)		Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II			Cu F
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291, PG II			Cu F
		<b>TOTALS</b>	1 4 Cu F

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

X Printed/Typed Name Karen Brocker Signature Karen Brocker Date 8/28/09

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS

STERICYCLE, INC.  
28161 N. Keith Drive  
Lake Forest, IL 60045

This is a Through Shipment

Phone #: (800) 633-9278

Applicable Permit Numbers

CT-BMW-005 NY-DECIL-033  
ME-BMT-033 RI-PW-TRAN-260  
NJ-DEP-19713 NH-0210

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above

Print/Type Name Karen Brocker Signature [Signature] Date 8/28/09

TRANSPORTER 2 / INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TRANSPORTER 3 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

TREATMENT FACILITY

7. DISCREPANCY INDICATION

8A. Designated Facility:

STERICYCLE, INC  
389 PARK EAST DRIVE  
WOONSOCKET, RI 02895  
(401) 789-5800  
Permit#: RI-053

8B. Alternate Facility:

STERICYCLE, INC  
1188 PORTER AVENUE  
HAW RIVER, NC 27258  
(336) 578-8900  
Permit#: 01-02-1

8C. Alternate Facility:

STERICYCLE, INC  
3472 PROGRESS DRIVE  
DUNKIRK, NY 14048  
(716) 388-4444  
Permit#: 9-0664-00019/00012

8D. Alternate Facility:

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above-indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name Kerdy Anthony Signature Kerdy Anthony Date 8-28-09

**1. Generator's Name, Address and Telephone Number**

10101 S. ...  
...  
...



CUSTOMER NUMBER 0000000000

GENERATOR'S REGISTRATION #

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II		4	16 Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II			Cu Ft.
		<b>TOTALS ▶</b>	4 16 Cu Ft.

3. Generator's Certification: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Printed/Typed Name Christie Jurena Signature Christie Jurena Date 8/7/09

GENERATOR

**4. TRANSPORTER 1 ADDRESS**

10101 S. ...  
...  
... This is a through shipment

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name Christie Jurena Signature Christie Jurena Date 8/7/09

TRANSPORTER

**5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:**

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

INTERMEDIATE HANDLER

**6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:**

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

INTERMEDIATE HANDLER

**7. DISCREPANCY INDICATION**

<input checked="" type="checkbox"/> 7A. Designated Facility: STERICYCLE, INC. 10101 S. ... ... ...	<input type="checkbox"/> 7B. Alternate Facility: STERICYCLE, INC. 10101 S. ... ... ...	<input type="checkbox"/> 7C. Alternate Facility: STERICYCLE, INC. 10101 S. ... ... ...	<input type="checkbox"/> 7D. Alternate Facility:
--	--	--	--

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name Kim Ben Signature Kim Ben Date 8-7-09

Generate this form by using Stericycle's manifest software and to be submitted electronically to the appropriate authority.



## **Waste Disposal and Hazard Communication**

### **REGULATED WASTE CONTAINMENT**

The bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling at a minimum:

- A. Liquid or semi-liquid blood or OPIM.
- B. Items contaminated with blood or OPIM and which release these substances in a liquid or semi-liquid state if compressed.
- C. Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling.
- D. Containment sharps.
- E. Pathological and microbiological wastes containing blood or OPIM.

### **GENERAL REGULATED WASTE CONTAINMENT**

- A. Regulated waste shall be placed in containers which are constructed to prevent leakage, appropriately labeled or color-coded, and closed prior to removal.
- B. If outside contamination of a regulated waste container occurs, it shall be placed in a second container which is constructed to prevent leakage, appropriately labeled or

color-coded, and closed.

- C. Disposal of regulated waste shall be in accordance with all Federal, State and Local standards.

#### **NEEDLES AND SHARPS DISPOSAL**

Discarding and containment of contaminated sharps:

- A. Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:
  - 1) Closable;
  - 2) Puncture resistant;
  - 3) Leakproof on the sides and bottom;
  - 4) Appropriately labeled or color-coded.
- B. During use containers for contaminated sharps shall be easily accessible to areas of use, upright, routinely replaced and not allowed to overfill.
- C. When moving containers of contaminated sharps they shall be closed and if leakage is likely, placed in a secondary closable, leakproof, and appropriately labeled or color-coded container.
- D. Reusable containers shall not be opened, emptied or cleaned manually.
- E. Used needles will be considered "regulated waste" regardless of the presence of infectious agents. Needle sheaths are not considered a "waste container" and self-sheathing devices will be disposed of in a sharps container.

- F. Sharps containers shall be sealed and replaced when the container becomes full.
- G. When small volumes of regulated waste are generated, they may be placed in a large holding container until the container is filled. The design of the container will be such that it will retain the waste without leakage of fluids during storage, transport or shipping.
- H. Full containers will be carefully closed, sealed and picked up for incineration or landfill disposition, according to current local waste disposal policy. Disposal containers will bear the appropriate biological hazard symbol.

## BOILED DISPOSABLES AND DRESSINGS

Contaminated dressings and disposable supplies (excluding sharps and needles) will be placed in a closable, leakproof plastic bag. If outside contamination of the primary container is likely, then a second leakproof, closable container will be used. The outside of the container will be labeled with an approved "BIOHAZARD" label or red bags/containers will be used for all infectious waste. The area where contaminated waste is stored will be marked with a biohazard sign. After proper containment and labeling, this waste will be disposed of with office waste for sanitary landfill disposal or incineration, according to current local waste disposal policy.

**FLUIDS/EXCRETIONS**

Suctioned fluids, excretions and secretions, will be carefully dispensed into drains connected to the sanitary sewage system.

**LABELING PROCEDURES/BIOHAZARD WARNING**

- A. Labels shall contain the word "BIOHAZARD" and the following Biohazard symbol:



**BIOHAZARD**

- B. Shall be fluorescent orange or orange-red with symbols and lettering in a contrasting color;
- C. Shall either be an integral part of the container or affixed to it in such a fashion as to prevent their loss or unintentional removal;
- D. Shall be affixed to:
1. Containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials;
  2. All containers used to store, transport, or ship blood or other potentially infectious materials except:
    - a) Red tags & bags may be substituted for labels.

- b) Containers of blood, blood products or components, which have been released for transfusion or clinical use.
- c) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal.

E. All Federal, State and Local regulations shall be observed.

## Four Women Health Services

### Waste packaging, labeling, and shipping procedures

1. Regulated waste shall be separated in accordance with 105 CMR 480.100. Clear separation between red bags, sharps and pathological waste occurs prior to shipping.
2. Pathological waste is placed in formalin and packaged in containers which are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color; and secured so as to prevent leakage and to preclude loss of contents during handling, storage and/or transport. These containers are placed in a freezer that is labeled with prominent signage indicating that the contents are regulated waste. Pathological waste remains stored in the freezer pending pickup. The freezer is located within a locked room that is labeled with biohazard identification.
3. Red bags and sharps are placed in containers which are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color; and secured so as to prevent leakage and to preclude loss of contents during handling, storage and/or transport. When these containers are full, they are placed in a locked closet used exclusively for waste storage. This closet has prominent signage indicating the space is used for the storage of regulated waste.
4. Off-site disposal is performed by a contacted waste disposal company. They provide corrugated cardboard boxes in which to package regulated waste. Pathological waste is packaged separately from red bags and sharps. Pathological waste is placed in the provided boxes and labeled with yellow "Pathological waste" stickers. Red bags and sharps containers are placed in provided boxes and labeled with red Biohazard stickers only.
5. Regulated waste is picked up monthly by a contracted waste disposal company. The contracted company for Four Women is: Stericycle. A record-keeping log is maintained on forms provided by the Department of Public Health. The record-keeping log forms shall be retained for three years and shall include the following information: the exact date of each shipment, the total number of containers, the type of waste, the total combined weight or volume, the name of the transporter, the verification of shipping papers generated with receipt of corresponding medical waste tracking forms for each shipment, and the printed name and signature of the person responsible for shipping the waste.
6. All necessary staff will be trained in the packaging, labeling and shipping of regulated waste. This training will be documented in employee files, and in the Waste Record Keeping log.

Marcus Gordon, MD \_\_\_\_\_ Date: \_\_\_\_\_



## LINENS/LAUNDRY

- A. Shall be handled as little as possible with a minimum of agitation;
- B. Shall be bagged or containerized where used without being sorted or rinsed;
- C. If wet and presents a reasonable likelihood of soaking through or leaking, shall be placed and transported in bags or containers which will prevent same;
- D. Shall be placed and transported in appropriately labeled or color-coded bags or containers;
- E. Employees who have contact with contaminated laundry shall wear protective gloves or other appropriate personal protective equipment;
- F. When shipping contaminated laundry to a facility that does not utilize universal precautions laundry containers shall be appropriately labeled or color-coded.

**Telephone Interview with Director of Community Sanitation Program**

**Dated: 01/25/09**

**Mr. Steven Hughes reports the agency did not investigate the Licensee, but inspected the facility. The Licensee was the point of contact for the facility, and recently submitted the P.O.C. on behalf of the Four Women Health Services**

**Herbu, Ichelle (DPH)**

---

**From:** Herbu, Ichelle (DPH)  
**Sent:** Wednesday, January 13, 2010 3:19 PM  
**To:** Button, Sharilyn (DPH)  
**Subject:** Request for Investigative Report

Hi Ms. Button:

I am not sure if you are the person I should be contacting, but was hoping you could help me.

I am a nurse investigator with DHPL, and I am currently investigating a case connected with, "The Four Women Health Services", on 150 Emory St. Attleboro, MA 02703 for an incident that occurred on 11/04/09. The case was a referral from the Bureau of Environmental Health Community of Sanitation Program.

I was wondering if your agency was or had conducted an investigation, if so, would it be possible to obtain the report and Statement of Deficiencies/Plan of Action. If I have contacted you in error, I apologize. However, can you please direct me to the right personnel?

Please let me know if you need any other information and thank you very much for your help in advance.

Sincerely,  
Ichelle

Ichelle Herbu  
Healthcare Investigator  
DPH, Division of Health Professions Licensure  
239 Causeway Street, 4th Floor  
Boston, MA 02114  
Tel: 617-973-0839  
Fax: 617-973-0985  
WEBSITE: [WWW.MASS.GOV/DPH](http://WWW.MASS.GOV/DPH)  
BLOG: [HTTP://PUBLICHEALTH.BLOG.STATE.MA.US](http://PUBLICHEALTH.BLOG.STATE.MA.US)

**Herbu, Ichelle (DPH)**

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**From:** Herbu, Ichelle (DPH)  
**Sent:** Wednesday, January 13, 2010 3:50 PM  
**To:** Hughes, Steven (DPH)  
**Subject:** Request for a Report

Hi Mr. Hughes,  
I am a Nurse Investigator with DHPL, and was recently assigned a case that involved a Licensee at "Four Women Health Services", 150 Emory Street, Attleboro, MA for an incident that occurred on 11/04/09. The case is a referral from your agency, and I was hoping you could forward me a copy of the report from the Community of Sanitation Program.

Thank you for your help in advance, and please feel free to contact me for any other information.  
Ichelle

Ichelle Herbu  
Healthcare Investigator  
DPH, Division of Health Professions Licensure  
239 Causeway Street, 4th Floor  
Boston, MA 02114  
Tel: 617-973-0839  
Fax: 617-973-0985  
WEBSITE: [WWW.MASS.GOV/DPH](http://www.mass.gov/dph)  
BLOG: [HTTP://PUBLICHEALTH.BLOG.STATE.MA.US](http://publichealth.blog.state.ma.us)

**Herbu, Ichelle (DPH)**

---

**From:** Herbu, Ichelle (DPH)  
**Sent:** Monday, January 25, 2010 11:51 AM  
**To:** 'steven.Hughes@state.ma.us'  
**Subject:** Request from The Board of Nursing

Hi Mr. Hughes:

Per our conversation earlier today, below is the e-mail I send on 01/13/10; however, I realized by our conversation that I am looking for the response from the "Four Women Health Service, 150 Emory Street, Attleboro, MA" (statement of deficit and plan of action).

Thank you again for your help,  
Ichelle

Ichelle Herbu  
Healthcare Investigator  
DPH, Division of Health Professions Licensure  
239 Causeway Street, 4th Floor  
Boston, MA 02114  
Tel: 617-973-0839  
Fax: 617-973-0985  
WEBSITE: [WWW.MASS.GOV/DPH](http://WWW.MASS.GOV/DPH)  
BLOG: [HTTP://PUBLICHEALTH.BLOG.STATE.MA.US](http://PUBLICHEALTH.BLOG.STATE.MA.US)

---

**From:** Herbu, Ichelle (DPH)  
**Sent:** Wednesday, January 13, 2010 3:50 PM  
**To:** Hughes, Steven (DPH)  
**Subject:** Request for a Report

Hi Mr. Hughes,  
I am a Nurse Investigator with DHPL, and was recently assigned a case that involved a Licensee at "Four Women Health Services", 150 Emory Street, Attleboro, MA for an incident that occurred on 11/04/09. The case is a referral from your agency, and I was hoping you could forward me a copy of the report from the Community of Sanitation Program.

Thank you for your help in advance, and please feel free to contact me for any other information.  
Ichelle

Ichelle Herbu  
Healthcare Investigator  
DPH, Division of Health Professions Licensure  
239 Causeway Street, 4th Floor  
Boston, MA 02114  
Tel: 617-973-0839  
Fax: 617-973-0985  
WEBSITE: [WWW.MASS.GOV/DPH](http://WWW.MASS.GOV/DPH)  
BLOG: [HTTP://PUBLICHEALTH.BLOG.STATE.MA.US](http://PUBLICHEALTH.BLOG.STATE.MA.US)

**Herbu, Ichelle (DPH)**

---

**From:** Hughes, Steven (DPH) [Steven.Hughes@state.ma.us]  
**Sent:** Monday, January 25, 2010 3:49 PM  
**To:** Herbu, Ichelle (DPH); Hughes, Steven (DPH)  
**Subject:** RE: Request from The Board of Nursing  
**Attachments:** Four Women response.pdf

Ms. Herbu,

It was a pleasure speaking with you this morning. I received the email this time – thanks for your patience. You noted that you already had a copy of the CSP inspection report [provided by HCQ]. Attached please find the facilities plan of correction letter.

Please let me know if you need any further assistance or if you have any additional questions.

Steve

\*\*\*\*\*

**Steven F. Hughes**  
Director, Community Sanitation Program  
Bureau of Environmental Health  
Massachusetts Department of Public Health  
250 Washington Street, 7th Floor  
Boston, MA 02108  
phone: (617) 624-5757 fax: (617) 624-5777

**email:** [steven.hughes@state.ma.us](mailto:steven.hughes@state.ma.us)

**website:** <http://www.mass.gov/dph/dcs>

\*\*\*\*\*

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**From:** Herbu, Ichelle (DPH) [mailto:Ichelle.Herbu@state.ma.us]  
**Sent:** Monday, January 25, 2010 11:51 AM  
**To:** Hughes, Steven (DPH)  
**Subject:** Request from The Board of Nursing

Hi Mr. Hughes:  
Per our conversation earlier today, below is the e-mail I send on 01/13/10; however, I realized by our conversation that I am looking for the response from the "Four Women Health Service, 150 Emory Street, Attleboro, MA" (statement of deficit and plan of action).

Thank you again for your help,  
Ichelle

**Ichelle Herbu**  
Healthcare Investigator  
DPH, Division of Health Professions Licensure  
239 Causeway Street, 4th Floor  
Boston, MA 02114  
Tel: 617-973-0839  
Fax: 617-973-0985  
WEBSITE: [WWW.MASS.GOV/DPH](http://WWW.MASS.GOV/DPH)  
BLOG: [HTTP://PUBLICHEALTH.BLOG.STATE.MA.US](http://PUBLICHEALTH.BLOG.STATE.MA.US)

10/25/2009

---

**From:** Herbu, Ichelle (DPH)  
**Sent:** Wednesday, January 13, 2010 3:50 PM  
**To:** Hughes, Steven (DPH)  
**Subject:** Request for a Report

Hi Mr. Hughes,

I am a Nurse Investigator with DHPL, and was recently assigned a case that involved a Licensee at "Four Women Health Services", 150 Emory Street, Attleboro, MA for an incident that occurred on 11/04/09. The case is a referral from your agency, and I was hoping you could forward me a copy of the report from the Community of Sanitation Program.

Thank you for your help in advance, and please feel free to contact me for any other information.  
Ichelle

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105 CMR: DEPARTMENT OF PUBLIC HEALTH  
MINIMUM REQUIREMENTS FOR THE MANAGEMENT OF MEDICAL OR BIOLOGICAL  
WASTE (STATE SANITARY CODE CHAPTER VIII)

105 CMR 480.000:

- Section
- 480.001: Purpose
  - 480.002: Authority
  - 480.003: Citation
  - 480.004: Scope
  - 480.010: Definitions
  - 480.020: Applicability
  - 480.100: Storage
  - 480.125: Home Sharps
  - 480.135: Sharps Collection Centers
  - 480.150: Approved Disinfection Methods
  - 480.200: Disposal
  - 480.300: Packaging, Labeling, and Shipping
  - 480.400: Shipping Papers
  - 480.425: Tracking Medical or Biological Waste for Treatment
  - 480.500: Procedures; Records; Record-Keeping Log
  - 480.550: Approval of Alternative Methods of Treatment, Storage, and Disposal
  - 480.600: Administration and Enforcement
  - 480.700: Severability

Copy of  
105 CMR 480.000

480.001: Purpose

The purpose of 105 CMR 480.000 is to set forth minimum requirements for the storage, treatment, disposal and transportation of medical or biological waste.

480.002: Authority

105 CMR 480.000 is adopted under authority of M.G.L. c. 94C, § 27A, and c. 111, §§ 3, 5 and 127A.

480.003: Citation

105 CMR 480.000 shall be known and may be cited as, 105 CMR 480.000: *Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII)*.

480.004: Scope

105 CMR 480.000 shall apply to all generators of medical or biological waste and Sharps Collection Centers established for the sole purpose of collecting sharps pursuant to M.G.L. c. 94C, § 27A, and shall also apply to home sharps, but not other waste generated by residents at private dwellings.

480.010: Definitions

**Affiliated Generator:** an associated, professional entity including a business partner, colleague or subsidiary that generates medical or biological waste.

**Approved Incineration Facility:** A facility approved and classified by the Massachusetts Department of Environmental Protection for incineration of waste or an out-of-state incinerator approved for incineration of waste by the appropriate regulatory agency.



480.010: continued

**Board of Health:** The appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth having the usual powers and duties of the Board of Health of a city or town or its authorized agent or representative.

**BSL 1, 2, 3 and 4:** Biosafety levels comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities specifically appropriate for the operations performed, the documented or suspected routes and ease of transmission of the infectious agents used, the severity of the disease, and the laboratory function or activity conducted according to the U.S. Department of Health and Human Services publications, *Biosafety in Microbiological and Biomedical Laboratories*, and the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

**Challenge Testing:** Quality control testing conducted during standard operating conditions, using a pre-determined biological indicator, to verify the effectiveness of approved disinfection methods for the treatment of medical or biological waste.

**Department:** Massachusetts Department of Public Health.

**Disinfection:** The reduction in level of microbial contamination.

**Generator:** See Waste Generator.

**Home Sharps (HS):** All spent non-commercially generated, hypodermic needles and lancets that have been used or are not in their original, intact and sealed packaging and that result from personal use or from pets at a residence or outside the home. The term Home Sharps does not include needles or lancets generated by home health aides, visiting nurses, or any other person providing a professional service in a private residence.

**Incinerate/Incineration:** The controlled flame combustion of materials in an enclosed system to thermally break down the solid waste and to render the waste noninfectious.

**Infectious or Physically Dangerous Medical or Biological Waste:** See "Medical or Biological Waste".

**Interment:** Burial in a cemetery

**ISTAATT:** The International Society on Analytical Analysis of Treatment Technologies (formerly the State and Territorial Association on Alternative Treatment Technologies – STAATT), or its successor, comprised of a group of state and international regulators, as well as other experts, which reviews and publishes guidance documents related to medical waste treatment technologies.

**Kiosk:** A secured, leak-proof receptacle or collection drop box, the contents of which are inaccessible to unauthorized personnel, designed to temporarily store approved sharps containers prior to pickup and transportation for treatment in accordance with 105 CMR 480.000.

**Medical and Biological Waste Alternative Treatment Review Group (MBWAT):** An advisory group, established by the Department, which is comprised of Department and Local Board of Health staff and, at the discretion of the Department, industry experts, that meets at a minimum annually to review alternative methods of treatment, storage or disposal of medical and biological waste and related issues.

**Medical or Biological Waste:** Waste that because of its characteristics may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

The following types of waste are identified and defined as medical or biological waste, and shall be subject to the requirements of 105 CMR 480.000:

(1) **Blood and Blood Products:** Discarded bulk human blood and blood products in free draining, liquid state; body fluids contaminated with visible blood; and materials saturated/dripping with blood. Blood and Blood Products shall not include: feminine hygiene products.

(2) **Pathological Waste:** Human anatomical parts, organs, tissues and body fluids removed and discarded during surgery, autopsy, or other medical or diagnostic procedures; specimens of body fluids and their containers; and discarded material saturated with body fluids other than urine. Pathological waste shall not

480.010: continued

include: Teeth and contiguous structures of bone without visible tissue, nasal secretions, sweat, sputum, vomit, urine, or fecal materials that do not contain visible blood or involve confirmed diagnosis of infectious disease.

(3) Cultures and Stocks of Infectious Agents and their Associated Biologicals: All discarded cultures and stocks of infectious agents and their associated biologicals, including culture dishes and devices used to transfer, inoculate, and mix cultures, as well as discarded live and attenuated vaccines intended for human use, that are generated in:

- (a) Laboratories involved in basic and applied research;
- (b) Laboratories intended for educational instruction; or
- (c) Clinical laboratories

(4) Contaminated Animal Waste: Contaminated carcasses, body parts, body fluids, blood or bedding from animals known to be:

- (a) Infected with agents of the following specific zoonotic diseases that are reportable to the Massachusetts Department of Agricultural Resources, Bureau of Animal Health pursuant to 105 CMR 300.140: African swine fever, Anthrax, Avian influenza – H5 and H7 strains and any highly pathogenic strain, Bovine spongiform encephalopathy (BSE), Brucellosis, Chronic wasting disease of cervids, Foot and mouth disease, Glanders, Exotic Newcastle disease, Plague (*Yersinia pestis*), Q Fever (*Coxiella burnetii*), Scrapie, Tuberculosis, Tularemia (*Francisella tularensis*); or
- (b) Infected with diseases designated by the State Epidemiologist and the State Public Health Veterinarian as presenting a risk to human health; or
- (c) Inoculated with infectious agents for purposes including, but not limited to, the production of biologicals or pharmaceutical testing.

(5) Sharps: Discarded medical articles that may cause puncture or cuts, including, but not limited to, all needles, syringes, lancets, pen needles, pasteur pipettes, broken medical glassware/plasticware, scalpel blades, suture needles, dental wires, and disposable razors used in connection with a medical procedure.

(6) Biotechnology By-Product Effluents: Any discarded preparations, liquids, cultures, contaminated solutions made from microorganisms and their products including genetically altered living microorganisms and their products.

Medical Waste Tracking Form: A paper or electronic form approved by the Department that provides confirmation to a generator of receipt of medical or biological waste by an off-site treatment facility.

Parametric Monitoring: Automated equipment that records critical parameters appropriate for the treatment process of rendering medical or biological waste non-infectious including but not limited to time, temperature, pressure and pH.

RG 1, 2, 3, and 4 Agents: Risk group levels resulting from the classification of the biohazardous agents based on their association with human disease, and the resulting severity of the disease, according to the U.S. Department of Health and Human Services publications, *Biosafety in Microbiological and Biomedical Laboratories* and the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

Record-Keeping Log: A log book with secured, consecutively numbered pages, which is used solely for the purpose of keeping and recording the information required by 105 CMR 480.500(B).

Sharps Collection Center (SCC): An identified site within a community that is established for the sole purpose of collecting home sharps pursuant to M.G.L. c. 94C, § 27A.

Shipping Papers: A form(s) which accompanies material shipped off-site and contains relevant information, as specified in 105 CMR 480.000 and Federal hazardous material transportation laws and regulations, regarding the material shipped.

Small-scale Generator (SSG): A waste generator, excluding home sharps users, that generates less than 50 pounds of medical or biological waste every 30 days.

480.010: continued

**Treatment Facility:** The off-site facility where medical or biological waste is rendered non-infectious prior to disposal as solid waste, in accordance with Massachusetts Department of Environmental Protection regulations or in the case of out-of-state disposal, in accordance with the appropriate regulatory agency responsible for solid waste disposal within that jurisdiction.

**Unprocessed Liquid Pathological Waste:** Whole body fluids, not derived mechanically or chemically, which are removed and discarded during surgery, autopsy, or other medical or diagnostic procedures.

**Waste Generator:** Any person, corporation, partnership, trust, association, society, organized group of persons, body politic and corporate, public agency, authority, department, office and political subdivision of the Commonwealth, that generates medical or biological waste except home sharps and other waste generated by residents at private dwellings. The term "waste generator" shall include but not be limited to hospitals, long-term care facilities, laboratories, clinics, physicians' and dentists' offices, schools, veterinarians, funeral homes, body piercing and body art facilities, trauma scene responders, and home health agencies providing services in private dwellings.

**480.020: Applicability**

(A) 105 CMR 480.000 shall apply to all medical or biological waste, as defined in 105 CMR 480.010, and shall be subject to all of the requirements in 105 CMR 480.000 until such waste has been disposed of in compliance with 105 CMR 480.200.

(B) The requirements of 105 CMR 480.000 shall not apply to medical or biological waste that is contained in a mixture which, due to the presence of other materials including but not limited to amalgam (mercury) and lead foil, is regulated by either hazardous or radioactive waste laws or regulations.

**480.100: Storage**

(A) All medical or biological waste, except sharps, shall be contained in a primary container which is a red, fluorescent orange or orange-red plastic bag that is impervious to moisture and has sufficient strength to resist ripping, tearing, or bursting under normal conditions of use and handling, and which meets the American Society for Testing Materials (ASTM) standard D1922-06a and ASTM D1709-04. Each primary container shall:

- (1) Be marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color; and
- (2) Be secured so as to prevent leakage and to preclude loss of contents during handling, storage, and/or transport.

(B) All areas for on-site storage of containers of medical or biological waste, excluding kiosks dedicated for the sole purpose of collecting home sharps pursuant to M.G.L. c. 94C, § 27A, shall be in an uncarpeted room or area with impervious, cleanable, non-absorbent flooring, used exclusively for waste storage.

(C) All on-site storage areas shall:

- (1) Have prominent signage indicating the space is used for the storage of regulated medical or biological waste;
- (2) Be designed or equipped to prevent unauthorized access;
- (3) Be designed or located to protect the waste from the elements and prevent access by vermin;
- (4) Provide sufficient space to allow for clear separation of regulated medical or biological waste from any other waste, when applicable;
- (5) Be adequate to accommodate the volume of regulated medical or biological waste generated prior to removal of waste for either waste transport off-site or on-site treatment, and
- (6) Be maintained such that there is no putrescence or off-site odors, using refrigeration when necessary.

480.100: continued

- (D) Sharps shall be segregated from other wastes and aggregated immediately after use in red, fluorescent orange or orange-red leakproof, rigid, puncture-resistant, shatterproof containers that resist breaking under normal conditions of use and handling, meet ASTM standard F2132-01, and that are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color.
- (E) Free draining blood and blood products and biotechnology by-product effluents shall be stored at all times in leakproof containers that are securely sealed.
- (F) Compactors or grinders shall not be used to process medical or biological waste until it has been rendered noninfectious and safe for disposal in accordance with 105 CMR 480.150.
- (G) All medical or biological waste, except from home sharps users, must be treated on-site or transported off-site for treatment at a minimum once per calendar year.

480.125: Home Sharps

- (A) Effective July 1, 2010, home sharps, as well as unopened packages of hypodermic needles and lancets, shall not be disposed of in solid municipal waste, including household waste, and shall be collected and disposed of in accordance with 105 CMR 480.125(B).
- (B) In accordance with M.G.L. c. 94C, § 27A, federal, state and local agencies as well as businesses and non-profit organizations may establish sharps disposal programs which may include, but not be limited to, the following:
  - (1) A program for safe, secure home sharps disposal;
  - (2) The establishment of sharps collection centers located at medical facilities and pharmacies;
  - (3) The establishment of sharps collection centers located in municipal facilities, including, but not limited to, fire stations, police stations, and public health offices; provided that sharps collection centers may be located at senior centers only for the purpose of disposing of medically necessary hypodermic needles; and
  - (4) Medical waste mail-back programs approved by the United States Postal Service.
- (C) All mail-back programs shall comply with the United States Postal Service, *New Standards for Mailing Sharps Waste and Other Regulated Medical Waste, 39 CFR Part 111*.

480.135: Sharps Collection Centers

- (A) A Sharps Collection Center shall be an identified site within a community that collects and manages home sharps. Operators of Sharps Collection Centers shall be responsible for arranging for the transportation and disposal of home sharps pursuant to 105 CMR 480.000.
- (B) In accordance with M.G.L. c. 94C, § 27A, the operator of a Sharps Collection Center shall:
  - (1) use only collection containers that meet the requirements of the U.S. Occupational Safety and Health Administration and the U.S. Department of Transportation and are marked with the international biohazard symbol;
  - (2) provide secure accessible collection containers on site;
  - (3) accept sharps from home sharps users that are in leak-proof, rigid, puncture resistant and shatterproof containers;
  - (4) provide appropriate transfer containers for home sharps users who fail to bring their sharps in suitable containers for placement in the collection container;

480.135: continued

- (5) have a written agreement with a medical waste transporter providing for regularly scheduled waste pickups; and
- (6) store, handle, transport and treat the collected waste in accordance with 105 CMR 480.000.

(C) Operators of Sharps Collection Centers, excluding kiosks, shall comply with the requirements set forth in 105 CMR 480.100(B), (C), (D), (F) and (G); 105 CMR 480.200(E); 105 CMR 480.300(A), (B), (D), (E) and (F); 105 CMR 480.400; 105 CMR 480.425 (A), (B), (C) and (D); 105 CMR 480.500(A), (B), (C), (H) and (I); as applicable.

(D) A kiosk used as a Sharps Collection Center may be attended or unattended, but shall be dedicated for the sole purpose of collecting home sharps pursuant to M.G.L. c. 94C, § 27A and shall:

- (1) meet all of the requirements of 105 CMR 480.135(B)(1), (2), (3), (4), and (5);
- (2) be marked and identified as a "Sharps Collection Drop Box" or with an equivalent designation and be clearly labeled with a contact name and emergency contact phone number for an individual(s) who either has knowledge about the specific kiosk including emergency response information, or who has immediate access to a person who possesses such knowledge;
- (3) be conspicuously labeled with the international biohazard symbol and the word "Biohazard" in a contrasting color;
- (4) be lined with a secondary container designed to prevent spillage, which meets the requirements of 105 CMR 480.300(B)(1), (2), (3), and (4); and
- (5) provide written directions in the appropriate language(s), if necessary, for the proper deposit of sharps containers, including but not limited to:
  - (a) "No loose needles, glass containers or paper/plastic bags"; and
  - (b) "Please do not leave sharps containers outside the kiosk".

(E) All kiosk operators shall comply with the requirements set forth in 105 CMR 480.100(C), (D) and (G); 105 CMR 480.200(E); 105 CMR 480.300(A), (B)(5), (D), (E) and (F); 105 CMR 480.400; 105 CMR 480.425(A), (B), (C) and (D); 105 CMR 480.500(A)(3) and (A)(4), (B), (C), (H), and (I); as applicable. Kiosk operators with a written agreement for direct pickup of home sharps by a medical waste transporter in accordance with M.G.L. c. 94C, § 27A shall be exempt from 105 CMR 480.300(F); 105 CMR 480.500(A)(3); and 105 CMR 480.500(C); as applicable.

(F) All Sharps Collection Centers including kiosks shall be inspected by the Board of Health once prior to initial operation to ensure compliance with the requirements of 105 CMR 480.000.

(G) Upon the completion of the initial inspection, the Board of Health shall notify the Department, within 30 days, of the location, and address of the Sharps Collection Center(s), including kiosks.

(H) The Department shall maintain a list of all Sharps Collection Centers, including kiosks, located within the Commonwealth, which are established by the Department or reported by local health officials upon completion of the initial inspection pursuant to 105 CMR 480.135(E).

(I) Collection of home sharps at a Sharps Collection Center shall be the point of generation of the waste. The Massachusetts Department of Environmental Protection may by policy or regulation exempt a Sharps Collection Center from the requirements in 310 CMR 16.00 (Site Assignment for Solid Waste Facilities) and 310 CMR 19.00 (Solid Waste Management), provided that the operator complies with the requirements in 105 CMR 480.135(A), (B), (C), (D), (E) and (F), as applicable.

480.150: Approved Disinfection Methods

(A) The following disinfection methods are approved, subject to any additional conditions that may be specified by the Department, to render medical or biological waste noninfectious, excluding pathological waste and contaminated animal waste which shall be disposed of at an approved incineration facility, by interment, or by an alternative method approved in writing by the Department, pursuant to 105 CMR 480.200:

480.150: continued

- (1) Steam disinfection / autoclaving;
- (2) Chemical disinfection;
- (3) Incineration at an approved incineration facility; or
- (4) Any other method approved in writing by the Department.

(B) The methods which rely on heat shall be evaluated for each load or cycle by using a recording thermometer, thermocouple, parametric monitoring device, thermal indicator strip, or by an equivalent method approved in writing by the Department.

(C) For any wastes that are rendered noninfectious by chemical disinfection, the chemical used shall be of demonstrated efficacy, as determined by the Department, against the challenge testing target or indicator organism and registered with:

- (1) The U.S. Environmental Protection Agency, Office of Pesticide Programs pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and
- (2) The Massachusetts Department of Agricultural Resources, Pesticide Bureau.

(D) All parametric monitoring equipment utilized in conjunction with any approved disinfection methods, including autoclaves, shall be calibrated at a minimum annually, by an individual who has received training from the manufacturer in the operations and maintenance of the equipment.

(E) Quarterly qualitative (growth/no growth) biological challenge testing shall be conducted during standard operations for all approved disinfection methods including autoclaves, but not incineration. Specifically:

- (1) Testing shall consist of spore strips or a retrievable alternative medium approved by the Department, which contain a  $1.0 \times 10^4$  minimum challenge population of a bacterial indicator organism that is most resistant to any aspect of the treatment technology as outlined in the most recent medical waste treatment technology guidelines established by The State and Territorial Association on Alternative Treatment Technologies (STAATT) or its successor The International Society of Analytical Analysis of Treatment Technologies (ISAATT);
- (2) Testing methodologies including the number, type and locations shall be in accordance with manufacturer's guidelines and procedures approved by the Department;
- (3) Analytical testing results (growth/no growth) should demonstrate a minimum bacterial spore reduction of  $4 \log_{10}$ ;
- (4) When a  $4 \log_{10}$  bacterial spore reduction has not been demonstrated (results indicate bacterial growth), an operations and mechanical systems assessment shall be conducted by a qualified individual who has received training from the manufacturer in the operations and maintenance of the equipment. Appropriate corrective actions shall be implemented, when warranted, including but not limited to mechanical adjustments and when applicable, recalibration of all parametric monitoring devices followed by re-treatment of the waste and additional challenge testing to confirm the effectiveness of any implemented corrective action;
- (5) In accordance with 105 CMR 480.500(B)(1)(f), the analytical test results shall be documented on the required record-keeping log form for medical or biological waste treated on site in conjunction with the date and all applicable corresponding process parameter results.
- (6) When implemented, corrective actions pursuant to 105 CMR 480.150(E)(4) shall be documented in detail, including the date, name of the individual implementing the corrective actions and a description of the work performed, on the back of the applicable record-keeping log form for medical or biological waste treated on-site.
- (7) All analytical test results shall be retained in the required record-keeping log for a period of three years.

## 480.200: Disposal

### (A) Blood and Blood Products:

(1) If the waste generator is connected to a municipal sewerage system or septic system, free draining blood and blood products, except blood saturated materials, may be disposed of directly into these systems unless such disposal is otherwise restricted by the authorized approving agency.

(2) If the waste generator is prohibited by the authorized approving agency from disposing of blood and blood products into the municipal sewerage system or septic system, blood and blood products shall be rendered noninfectious in accordance with 105 CMR 480.150 prior to disposal in a sanitary landfill approved by the Massachusetts Department of Environmental Protection or in case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval.

### (B) Pathological Waste:

Pathological wastes shall be disposed of at an approved incineration facility or by interment provided however that unprocessed liquid pathological waste may also be disposed of in accordance with 105 CMR 480.200(A).

### (C) Blood Saturated Materials, Cultures and Stocks of Infectious Agents and their Associated Biologicals, Dialysis Waste and Laboratory Waste:

Blood saturated materials, cultures and stocks of infectious agents and their associated biologicals, dialysis waste and laboratory wastes shall be:

(1) Rendered noninfectious onsite in accordance with 105 CMR 480.150 and disposed of in a sanitary landfill approved by the Massachusetts Department of Environmental Protection or in the case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval; or

(2) Placed in a secondary container pursuant to 105 CMR 480.300 (B) and stored in accordance with 105 CMR 480.100 prior to transport to an approved off-site facility to be rendered noninfectious in accordance with 105 CMR 480.150.

### (D) Contaminated Animal Waste:

Contaminated animal wastes shall be disposed of at an approved incineration facility, by proper burial, by interment or by an alternative method approved in writing by the Department. Unprocessed liquid pathological waste may also be disposed of in accordance with 105 CMR 480.200(A) and tissue may also be disposed of in accordance with 105 CMR 480.200(C).

### (E) Sharps:

Containers of sharps shall either be:

(1) Disposed of by incineration at an approved incineration facility; or

(2) Rendered noninfectious as set forth in 105 CMR 480.150 and processed by grinding or other effective method to eliminate the physical hazard of the sharps and disposed of in a sanitary landfill approved by the Massachusetts Department of Environmental Protection, or in the case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval within that jurisdiction.

### (F) Biotechnology By-product Effluents:

Biotechnology by-product effluents that contain RG3 or RG4 agents or are from BSL3 and BSL4 facilities shall not be removed from the site of the waste generator unless all viable microorganisms, whether containing recombinant DNA or not, have been rendered non-infectious in accordance with 105 CMR 480.150. All other biotechnology by-product effluents shall not be removed from the site of the waste generator unless the viable microorganisms including those that might contain recombinant DNA molecules have been rendered noninfectious in accordance with 105 CMR 480.150 however, BSL1 or BSL2 facilities may allow biotechnology by-product effluents that contain RG1 or RG2 agents to be removed from the site prior to treatment if the facility meets the below listed requirements and maintains compliance with the Massachusetts Uniform State Plumbing Code (248 CMR) and the Massachusetts Department of Environmental Protection regulations 314 CMR 7.00 (industrial wastewater permit):

480.200: continued

(1) The facility has organized and implemented an Institutional Biosafety Committee (IBC) which is specifically comprised of:

(a) no fewer than five members who collectively have experience and expertise in recombinant DNA technology and/or RG1 and RG2 agents as appropriate, as well as the capability to assess the safety of the biological research; and to identify any potential risk to public health or the environment posed by the biotechnology by-product effluent; and

(b) at least two members, not affiliated with the institution, apart from membership on the IBC, who shall represent the interests of the surrounding community with respect to health and environmental protection (such members may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons in the community active in medicine, occupational health, or environmental science).

(2) The Institutional Biosafety Committee (IBC) shall meet, at a minimum, once a year to evaluate the public health and environmental risks associated with all biotechnology-by-product effluents generated by the facility and to determine the applicability of conditions, including appropriate effluent treatment requirements, for disposal of these wastes according to provisions of the Uniform State Plumbing Code (248 CMR);

(3) The IBC shall make recommendations to management regarding the appropriate effluent treatment requirements for facility waste at least once a year and document those recommendations in the required record-keeping log;

(4) IBC meetings may be open to the public; and

(5) Minutes of all IBC meetings shall be retained as an appendix to the required record-keeping log, as specified in 105 CMR 480.500(G).

480.300: Packaging, Labeling, and Shipping

(A) Every container or bag of waste that has not been rendered noninfectious in accordance with 105 CMR 480.150 shall be colored and labeled according to the requirements of 105 CMR 480.100(A) or 105 CMR 480.100(D), as applicable, to indicate that it contains infectious or physically dangerous medical or biological waste.

(B) Every container or bag of waste that has not been rendered noninfectious in accordance with 105 CMR 480.150 and which will be transported off the premises of the waste generator shall, in addition to the requirements of 105 CMR 480.300(A), be placed in secondary containers which are:

(1) Rigid;

(2) Leak resistant;

(3) Impervious to moisture;

(4) Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling; and

(5) Sealed to prevent leakage during handling and transport.

(C) Prior to transport for off-site disposal, waste that has been rendered noninfectious by a method other than incineration shall be labeled or otherwise marked so as to clearly identify it as noninfectious medical or biological waste and to identify the waste generator responsible for the treatment. Such waste may be disposed of in the same manner as waste that is not regulated by 105 CMR 480.000, except for sharps, which shall be disposed of in accordance with the requirements of 105 CMR 480.200(E).

(D) All shipping of medical or biological waste shall comply, as applicable, with transportation requirements of M.G.L. c. 111, § 31A regarding permitting of waste haulers by local Boards of Health, United States Postal Service, 39 CFR Part 111 and the U.S. Department of Transportation regulations, 49 CFR Parts 171-180.

(E) Waste generators, small-scale generators, and Sharps Collection Centers shall not ship any container of medical or biological waste which shows evidence of leaking or which is otherwise torn or damaged.



480.300: continued

(F) Unless there is a more restrictive provision imposed by a Board of Health or the Massachusetts Department of Environmental Protection concerning individuals who are authorized to transport their own waste, small-scale generators and Sharps Collection Centers may transport their own waste, except biotechnology by-product effluents, within the Commonwealth, provided that they do not transport more than 50 pounds every 30 days. Small-scale generators or operators of Sharps Collection Centers shall be responsible for arranging transportation by a dependable individual who has knowledge about the waste being shipped, including emergency response information.

480.400: Shipping Papers

(A) Waste generators, small-scale generators that transport their own waste in accordance with 105 CMR 480.300(F), and Sharps Collection Centers, shall prepare shipping papers in accordance with 105 CMR 480.400 before shipping waste off-site that has not been rendered noninfectious prior to transport. A designee shall be appointed to prepare, sign and maintain such shipping papers.

(B) The shipping papers shall be signed and dated by the waste generator's, small-scale generator's, or Sharps Collection Center's designee and must include the following information:

- (1) The name, address, and phone number of the waste generator along with a contact name and emergency contact number for an individual who either has knowledge about the waste material, including emergency response information, or who has immediate access to a person who possesses such knowledge and information;
- (2) A description of the waste to be shipped;
- (3) The total quantity of waste to be shipped;
- (4) The type of container or containers in which waste is to be transported; and
- (5) The destination of the delivery.

(C) All waste generators, including small-scale generators and Sharps Collection Centers, shall maintain a copy of all shipping papers, with the record-keeping log pursuant to 105 CMR 480.500(H), for a period of 375 days after the material is accepted by the transporter, or for any longer period of time as specified in federal hazardous material transportation laws and regulations.

(D) Small-scale generators and Sharps Collection Centers that transport their own waste in accordance with 105 CMR 480.300(F) shall maintain original shipping papers, with the record-keeping log, for a period of 375 days after the material is delivered to the site of an affiliated generator, or for any longer period of time as specified in federal hazardous material transportation laws and regulations.

(E) Waste generators, small-scale generators and Sharps Collection Centers shall make all shipping papers available upon request by the Department or the Board of Health at all reasonable times.

480.425: Tracking Medical or Biological Waste for Treatment

(A) Waste generators, small-scale generators and Sharps Collection Centers, shall confirm within 30 days of shipment the receipt at a treatment facility of all medical or biological waste shipped off-site for treatment pursuant to 105 CMR 480.300. Confirmation shall be documented on a paper or electronic medical waste tracking form, approved by the Department. The medical waste tracking form must include all shipping paper information in accordance with 105 CMR 480.400(B), as well as documentation of the treatment facility name, address and telephone number with a contact person who has knowledge about the waste material received or who has immediate access to a person who possesses such knowledge. A completed copy of the medical waste tracking form must be retained with the corresponding shipping paper(s) and the record keeping log required by 105 CMR 480.500(B) for a period of 375 days.

480.425 continued

(B) If the waste generator, small-scale generator or Sharps Collection Center does not receive a hard copy or cannot access for download an approved electronic copy of the completed medical waste tracking form pursuant to 480.425(A) within 30 days after shipment, the waste generator, small-scale generator or Sharps Collection Center shall report this fact to the Department.

(C) Small-scale generators and Sharps Collection Centers conducting in-state transportation of their own medical or biological waste to an affiliated generator, in accordance with 105 CMR 480.300(F), shall retain the original shipping papers signed by the small-scale generator's or Sharps Collection Center's designee and a designee from the affiliated generator receiving the medical or biological waste, in lieu of a medical waste tracking form, for a period of 375 days, pursuant to 105 CMR 480.400(C). In addition, the small-scale generator or Sharps Collection Center shall document all applicable information in the required record-keeping log for off-site treatment pursuant to 105 CMR 480.500(B)(2) and the Department's Record-Keeping Guidelines for Medical or Biological Waste. The "shipping paper" and "tracking form" boxes should be checked to reflect that both provisions have been satisfied.

(D) Waste generators, small-scale generators, and Sharps Collection Centers receiving medical or biological waste from appropriate and affiliated small-scale generators, or Sharps Collection Centers, shall:

(1) document all applicable information in the required record-keeping log for off-site treatment, if it is to be shipped off-site, pursuant to 105 CMR 480.500(B)(2), and the Department's Record-Keeping Guidelines for Medical or Biological Waste, with a separate entry dedicated to each delivery received. The "shipping paper," "tracking form" and "printed name / signature" boxes should remain blank until such time as all of the waste is shipped off-site for treatment. The next shipment for off-site treatment shall include all of the previous medical or biological waste received from small-scale generators or Sharps Collection Centers and any waste generated on-site since the last shipment.

(2) document all applicable information in the required record-keeping log for on-site treatment, if it is to be treated on-site, pursuant to 105 CMR 480.500(B)(1)(b), 105 CMR 480.500(B)(1)(c), and 105 CMR 480.500(B)(1)(g)(i), as well as the Department's Record-Keeping Guidelines for Medical or Biological Waste, with a separate entry dedicated to each delivery received. The remaining information shall be documented at the time of treatment.

(E) Waste generators or small-scale generators receiving sharps from home sharps users shall:

(1) document all applicable information in the required record-keeping log for off-site treatment, if it is to be shipped off-site, pursuant to 105 CMR 480.500(B)(2), and the Department's Record-Keeping Guidelines for Medical or Biological Waste, with a separate entry dedicated to each delivery received. The "shipping paper," "tracking form" and "printed name / signature" boxes should remain blank until such time as all of the waste is shipped off-site for treatment. The next shipment for off-site treatment shall include all of the previous medical or biological waste received from home sharps users and any waste generated on-site since the last shipment.

(2) document all applicable information in the required record-keeping log for on-site treatment, if it is to be treated on-site, pursuant to 105 CMR 480.500(B)(1)(b), 105 CMR 480.500(B)(1)(c), and 105 CMR 480.500(B)(1)(g)(ii), as well as the Department's Record-Keeping Guidelines for Medical or Biological Waste, with a separate entry dedicated to each delivery received. The remaining information shall be documented at the time of treatment.

480.500 Procedures; Records; Record-Keeping Log

Waste generators, small-scale generators, and Sharps Collection Centers, shall:

(A) Develop written procedures, as applicable, for rendering waste noninfectious and to assure effectiveness and compliance with the requirements set forth in 105 CMR 480.000. These shall include:

480.500 continued

- (1) Procedures for the identification of types, quantities and disposition of regulated medical or biological waste including waste approved for disposal in accordance with 105 CMR 480.200(A)(1);
- (2) Procedures for safe handling and transportation within the facility from the point of generation to the point of storage and/or treatment;
- (3) Confirmation of U.S. Department of Labor, Occupational Safety and Health Administration's Bloodborne Pathogen Training for all individuals who may potentially handle medical or biological waste;
- (4) The listing of a contact name and emergency contact number for an individual(s) who either has knowledge about the waste material, including emergency response information, or who has immediate access to a person who possesses such knowledge and information;
- (5) A description of on-site regulated medical or biological waste storage areas, including those used for short-term storage, which detail the ventilation and capacity of the storage areas, and the duration waste will be retained in each area.

(B) Maintain a current record-keeping log, on forms provided by the Department or alternate forms, if approved by the Department and which provide at a minimum all of the same required information, for all medical or biological waste either treated on-site in accordance with 105 CMR 480.150 or shipped off-site for treatment, excluding waste approved for disposal pursuant to 105 CMR 480.200(A)(1). The record-keeping log shall have secured, consecutively numbered pages and have on its cover the name of the facility, the name of the owner and operator, if applicable, and in large print the words "Medical/Biological Waste Record-Keeping Log." The record-keeping log forms shall be retained for three years and shall include the information listed below.

- (1) The record-keeping log for medical or biological waste treated on-site shall specify:
  - (a) The exact date of each treatment;
  - (b) The quantity of waste treated;
  - (c) The type of waste;
  - (d) The on-site treatment method with documentation of applicable process parameters including, but not limited to, time, pressure, temperature, and pH;
  - (e) The printed name and signature of the person responsible for treatment;
  - (f) Challenge testing/quality control (QC) analytical (growth/no growth) results and
  - (g) The following additional information, if applicable:
    1. in cases where waste generators, small-scale generators or Sharps Collection Centers receive waste from an affiliated small-scale generator or a Sharps Collection Center, prior to on-site treatment:
      - a. the exact date that the waste was received;
      - b. the term "SSG" for small-scale generator or "SCC" for Sharps Collection Center, whichever applies; and
      - c. the name and address of the affiliated small-scale generator or Sharps Collection Center delivering the waste.
    2. in cases where waste generators or small-scale generators receive sharps from a home sharps user prior to on-site treatment:
      - a. the exact date that the home sharps were received; and
      - b. the term "HS" for home sharps.
- (2) The record-keeping log for medical or biological waste shipped off-site for treatment shall specify:
  - (a) The exact date of each shipment;
  - (b) The total number of containers;
  - (c) The type of waste;
  - (d) The total combined weight or volume;

480.500 continued

- (e) The name of the transporter with transporter identification number (if applicable), or:
    - 1. in cases where small-scale generators or Sharps Collection Centers conduct in-state transportation of their own medical or biological waste to an affiliated generator:
      - a. the name and address of the affiliated generator that received the waste in the transporter column; and
      - b. the term "SSG" for small-scale generator or "SCC" for Sharps Collection Center, whichever applies, in the ID column.
    - 2. in cases where waste generators, small-scale generators or Sharps Collection Centers receive waste from an affiliated small-scale generator or a Sharps Collection Center, prior to shipment off-site for treatment:
      - a. the name and address of the affiliated small-scale generator or Sharps Collection Center delivering the waste in the transporter column; and
      - b. the term "SSG" for small-scale generator or "SCC" for Sharps Collection Center, whichever applies, in the ID column.
    - 3. in cases where waste generators or small-scale generators receive sharps from home sharps users prior to shipment off-site for treatment, the term "HS" in the ID column.
  - (f) The verification (via check box) of shipping papers generated with receipt of corresponding medical waste tracking forms for each shipment; and
  - (g) The printed name and signature of the person responsible for shipping the waste.
- (C) Develop, maintain and incorporate into the record-keeping log a written contingency plan for spills and accidents and have available tools and materials sufficient to implement these procedures in case of a spill or accident.
- (D) Retain results of annual calibration procedures for parametric monitoring equipment with the record-keeping log for three years, if applicable.
- (E) Retain all analytical Q.C. test results with the required record-keeping log for three years.
- (F) Retain with the required record-keeping log, a copy of all applicable registrations and material safety data sheets (MSDS) for chemicals used in approved disinfection methods pursuant to 105 CMR 480.150.
- (G) Retain with the required record-keeping log, a list of all IBC members, past and present, with credentials, minutes of all IBC meetings and recommendations of the IBC pursuant to 105 CMR 480.200(F)(3) and 105 CMR 480.200(F)(5).
- (H) Retain with the required record-keeping log, copies of all shipping papers with corresponding medical waste tracking forms, or the signed original shipping papers in the case of small-scale generators or Sharps Collection Centers that transport their own waste within the Commonwealth pursuant 105 CMR 480.400(D), for a period of 375 days.
- (I) Make all such procedures, records and record-keeping logs accessible and available upon request to the Department and the Board of Health at all reasonable times.

480.550: Approval of Alternative Methods of Treatment, Storage, and Disposal

The Department may approve, in writing, alternative methods not otherwise authorized by 105 CMR 480.000 for the treatment, storage or disposal of medical or biological waste under the following conditions:

- (A) An application has been completed, signed, submitted and accepted by the Department;
- (B) The method has been validated through scientific studies acceptable to the Department;
- (C) The method has been reviewed and approved by the Department's Medical and Biological Waste Alternative Treatment Review Group (MBWAT) and

480.550 continued

(D) If the waste is to be transported off-site, the waste treatment facility has been approved by the Massachusetts Department of Environmental Protection or, if shipped out of state, by the appropriate regulatory agency in that state.

480.600: Administration and Enforcement

(A) Scope. The following provisions shall cover the administration and enforcement of 105 CMR 480.000 in lieu of 105 CMR 400.000: *The State Sanitary Code, Chapter I: General Provisions.*

(B) Inspection Authority. In order to properly carry out their respective responsibilities under 105 CMR 480.000 and to properly protect the health and well-being of the residents of the Commonwealth, the Department, in the case of generators which are health care facilities licensed by the Department, and the Boards of Health and the Department, in the case of all other generators, or the authorized agent or representative of either, are authorized to enter, examine, or survey at any reasonable time such places as they consider necessary to carry out the provisions of 105 CMR 480.000

(C) Notices. If, as a result of any inspection or investigation, the Board of Health or the Department finds a violation of 105 CMR 480.000, the Board of Health or the Department shall issue a notice to the waste generator that sets forth the nature of the violation and warns said generator that a second such violation may result in legal action. However, the Board of Health and the Department shall have the authority to initiate proceedings to enforce 105 CMR 480.000 without prior notice in those circumstances in which the Board of Health or the Department determines that there is an imminent risk to public health or safety.

(D) Penalty. Any person who violates any provision of 105 CMR 480.000 other than 105 CMR 480.200 shall, upon conviction, be fined not less than \$ 100 nor more than \$ 500 per day of violation. The penalty for violation of any provision of 105 CMR 480.200 shall, upon conviction, be a fine of not more than \$ 25,000 or up to two years in a house of correction.

(E) Injunctions. The Department may seek to enjoin violations of 105 CMR 480.000 pursuant to M.G.L. c. 111, §127A and to M.G.L. c. 214, § 3(12). Boards of Health may seek to enjoin such violations in accordance with applicable law, including M.G.L. c. 111, §127A.

(F) Variance.

(1) The Boards of Health may vary the application of any provision of 105 CMR 480.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided that the decision of the Board of Health shall not conflict with the intent of any minimum standard established by 105 CMR 480.000. No such variance shall be effective until the Board of Health submits it to the Department and it has also been approved by the Department. If the Department fails to comment on the variance within 30 days of receipt, it shall be deemed to be approved. Any variance granted by a Board of Health shall be in writing. A copy of any such variance shall, while it is in effect, be available to the public at all reasonable hours in the office of the Board of Health.

(2) Any variance or other modification to any of the provisions of 105 CMR 480.000 that are authorized by a Board of Health shall be subject to such qualification, revocation, suspension, or expiration as the Board of Health expresses in its grant. A variance or other modification to the provisions of 105 CMR 480.000 may otherwise be revoked, modified, or suspended, in whole or in part, only after the holder thereof has been notified in writing and has been given an opportunity to be heard.

480.600 continued

(G) Removal of Nuisance by Board of Health. Pursuant to the provisions of M.G.L. c. 111, § § 122 through 125, a Board of Health may also act to abate any nuisance that is caused by a failure to comply with the provisions of 105 CMR 480.000 thereby endangering or materially impairing the health, safety, and well-being of the public, and to charge the responsible person or persons with any and all expenses incurred.

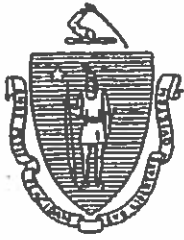
(H) Notice Concerning Violations by Registered Professionals. If the Department or Board of Health issues a notice pursuant to 105 CMR 480.600(C) or obtains a conviction and/or fine pursuant to 105 CMR 480.600(D) with respect to a registered health care professional, the Department or Board of Health shall notify the appropriate professional registration board.

**480.700: Severability**

If any section, paragraph, sentence, clause, phrase or word of 105 CMR 480.000 shall be declared invalid for any reason whatsoever, that decision shall not affect any other portion of 105 CMR 480.000, which shall remain in full force and effect; and to this end the provisions of 105 CMR 480.000 are hereby declared severable.

**REGULATORY AUTHORITY**

105 CMR 480.000: M.G.L. c. 111, §§ 3, 5 and 127A.



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Environmental Health  
Community Sanitation Program  
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DEC 16 2009

Christie L. Jurena, MPH, RN, MS, WHNP-BC  
Administrator  
Four Women Health Services  
150 Emory Street  
Attleboro, MA 02703

December 12, 2009

Re: Complaint investigation re: compliance with requirements for medical waste management

Dear Ms. Jurena,

On November 4, 2009, the Department of Public Health's Community Sanitation Program (CSP) and the Attleboro Health Department conducted a compliance inspection at Four Women Health Services located at 150 Emory Street, Attleboro, MA. This inspection was conducted in accordance with M.G.L. c. 111, §127A, and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), in response to an alleged violation of 105 CMR 480.200 – illegal disposal of medical or biological waste as solid municipal waste. In addition, the complaint and this investigation report have been forwarded to the Department's Division of Health Care Quality which is responsible for investigation of complaints involving clinics licensed pursuant to 105 CMR 140.000.

#### FINDINGS

Based on observations made during the on-site inspection, the CSP determined that Four Women Health Services had numerous deficiencies in its medical or biological waste management and was not in compliance with the following requirements of 105 CMR 480.000:

- The area used for medical waste storage lacked appropriate signage indicating the presence of regulated medical or biological waste. A single loose red bag of unidentified medical or biological waste was present (but not labeled for shipment) on the floor of a multi-purpose storage/hot water heater room without clear signage [105 CMR 480.100(C)(1)].
- The area used for medical waste storage lacked appropriate security to prevent unauthorized access [105 CMR 480.100(C)(2)].

- As currently configured the storage area does not allow clear separation of regulated medical waste (red bags/sharps/pathological waste) [105 CMR 480.100(C)(4)].
- Required written procedures were not maintained for the proper management of medical or biological waste [105 CMR 480.500(A) and 105 CMR 480.500(I)].
- Required medical waste record-keeping log was not maintained [105 CMR 480.500(B) and 105 CMR 480.500(I)].
- Required written contingency plan for spills and accidents was not maintained [105 CMR 480.500(C) and 105 CMR 480.500(I)].

## **CORRECTIVE ACTIONS**

Based on the November 4, 2009 inspection, the Department requires the following corrective actions:

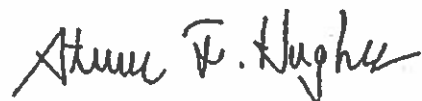
1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.
2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.
3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.
4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.
5. Four Women Health Services must provide to the Department documentation including medical waste record-keeping logs and shipping papers / tracking forms for all waste sent off-site for treatment since August 1, 2008.
6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.
7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.



Four Women Health Services must provide a response in writing regarding these corrective actions to the Community Sanitation Program by January 15, 2010. Please be advised that pursuant to 105 CMR 480.600(C), this letter constitutes notice to Four Women Health Services of the nature of these current violations and that any additional violations of 105 CMR 480.000 may result in legal action.

Please feel free to contact me at (617) 624-5757 if you have further questions regarding this matter.

Sincerely,



Steven F. Hughes  
Director, Community Sanitation Program

CC:

Suzanne K. Condon, Associate Commissioner, Director, BEH  
James Ballin, Deputy General Counsel, DPH  
Lisa Noling Snellings, Deputy General Counsel, DPH  
Lillian Jette, DHCQ  
Sherman Lohnes, DHCQ  
James P. Mooney, Health Director, Attleboro