Biological Waste Management Plan

Part I – The Basic Design – 105 CMR 480

1. Introduction:

In accordance with the new 105 Code of Massachusetts Regulations (CMR) 480, entitled Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII), which went into effect on July 11, 2008, Tufts University and all its subsidiaries and partners, have designed this plan to be in compliance with the law.

2. Purpose of the Ruling - 480.001

The new regulation is designed to set forth minimum requirements for the storage, treatment, disposal and transportation of medical, animal or biological waste.

3. Scope of the Plan - 480.004

This plan applies to all of Tufts and Tufts subsidiary generators of medical or biological waste and Sharps Collection programs.

4. Definitions – 480.010

Affiliated Generator: an associated, professional entity including a business partner, colleague or subsidiary that generated medical or biological waste, i.e., Tufts Dental School, Tufts Cummings School of veterinary medicine, Tufts Walpole clinic, Tufts University – Medford Campus, Tufts Medical School, etc. This plan includes descriptions of waste management types which may be utilized by each subsidiary, based on work and waste generated.

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/NA): 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, http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm ,and the NIH Guidelines for Research involving Recombinant DNA Molecules, http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html .
**Challenge Testing:** Quality control testing conducted during standard operating conditions, using a predetermined 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.

**Interment:** Burial in a cemetery

**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, necropsy, 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 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:
   - laboratories involved in basic and applied research;
   - laboratories intended for educational instruction; or
   - clinical laboratories

4. **Contaminated Animal Waste:** Contaminated carcasses, body parts, body fluids, blood or bedding from animals known to be:
   - 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 burnetti), Scrapie, Tuberculosis, Tularemia (Francisella tularensis); or
   - infected with diseases designated by the State Epidemiologist and State Public Health Veterinarian as presenting a risk to human health; or
   - 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/plastic ware, scalpel blades, suture needles, dental wires, and disposable razors used in connection with medical procedures
(6) Biotechnology By-Product Effluents: Any discarded preparations, liquids, cultures, contaminate 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, and 3 (4 NA) Agents: Risk group levels resulting from the classification of the biohazardous agents based on their association with human disease, as found in the BMBL, http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

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

Shipping Papers: Forms which accompany material shipped off-site and which contain 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 that generates less than 50 pounds of medical or biological waste every 30 days. Tufts and its subsidiaries are considered a large scale generator.

Treatment Facility: An off-site facility where medical or biological waste is rendered non-infectious prior to disposal as solid waste, in accordance with Mass DEP or out of state disposal, in accordance with the appropriate regulatory agency responsible for solid waste disposal within that jurisdiction.

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. The term “waste generator” shall include but not be limited to hospitals, long-term care facilities, laboratories, clinics, physicians’ and dentists’ offices, schools, veterinarians, and trauma scene responders.

5 Applicability - 480.020

(A) 105 CMR 480.00 applies to all medical or biological waste, as defined in 105 CMR 490.010, 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.

6. Storage – 480.100

(A) Medical or biological waste, depending on waste stream, campus or subsidiary location, is handled/contained in primary containers which are compatible with the regulations, but which
also allow for proper treatment and final disposition of the particular waste stream. All bags are impervious to moisture and have sufficient strength to resist ripping, tearing, or bursting under normal conditions of use and handling.

While some locations do in fact use the red, fluorescent orange or orange-red plastic bags, others use clear bags with the biohazard symbol clearly marked on the bag, the symbol being one that disappears upon autoclave sterilization, thus making disposal in regular waste stream manageable from a downstream worker or environment perspective. Therefore:

a. All bags are marked with the universal biohazard warning symbol, and
b. Are secured to prevent leakage and to preclude loss of contents during handling, storage, decontamination and or transport.

(B) All on-site storage areas are in a non-carpeted room or area with impervious, cleanable, non-absorbent flooring, used exclusively for waste storage prior to decontamination or shipping.

(C) All on-site storage/treatment areas also have:

a. Prominent signage indicating the space is used for storage/treatment of regulated medical or biological waste
b. Are designed or equipped to prevent unauthorized access
c. Are designed or located to protect waste from the elements and prevent access by vermin
d. Provide sufficient space to allow for clear separation of regulated medical or biological waste from any other waste, when applicable, and
e. Are adequate to accommodate the volume of regulated medical or biological waste generated prior to on-site treatment or transport to off-site waste management, and
f. Are maintained so that there is no putrescence or off-site odors, using refrigeration when necessary.

(D) Sharps management is segregated from other waste streams and controlled by a sharps management containerized system throughout the University and its subsidiaries. (This is discussed under “Sharps Management Program”)

(E) Free draining blood and blood products, if any, and biotechnology by-product effluents are stored at all times in leak proof containers that are securely sealed.

(F) Compactors or grinders are not used in any location at the University or any of its subsidiaries.

(G) All medical or biological waste is treated on-site or transported off-site for treatment at on a usual daily, weekly or monthly basis. Never more seldom than this. Sharps, which will be discussed separately, are removed from all locations on a weekly or monthly basis, depending on generation levels.

7. **Approved Disinfection Methods – 480.150**

(A) The following disinfection methods, approved by the Department, to render medical or biological waste noninfectious, excluding pathological waste and contaminate animal waste which shall be disposed of at an approved incineration facility, by interment, or by an alternative method approved by the Department, are:

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) Tufts and its subsidiaries use steam disinfection/autoclaving, temperature/pressure/time, or gas plasma for all of its biological waste management. These operations are managed under the following requirements:

1) Each load or cycle is evaluated by using a recording thermometer, thermocouple, parametric monitoring device or thermal indicator strip.
2) All parametric monitoring equipment utilized in conjunction with the approved disinfection method, including autoclaves, is calibrated at a minimum of annually, by an individual who has received training from the manufacturer in the operations and maintenance of such equipment.

3) Quarterly qualitative (growth/no growth) biological challenge testing is conducted during standard operations for all approved methods, including autoclaves. In some/many locations, biological challenge testing is performed on a monthly, weekly or daily basis, depending on use of autoclave.

4) 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.

5) When implemented, or when necessary, all 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 for a period of three years.

8.0 – Disposal – 480.200

A. Blood and Blood Products
   1. In locations where one of the University or it’s subsidiary generators 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 restricted by an approving agency.
   2. If this cannot be done, then the blood and blood products are rendered non-infectious on-site prior to disposal.

B. Pathological Waste:
   This particular category is not currently applicable to any Tufts location.
   Pathological waste is 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 are:
   1. Rendered noninfectious onsite, in accordance with 105 CMR 480.150 and disposed of in a sanitary landfill approved by the Mass DEP 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 4890.150.

D. Contaminated Animal Waste:
   Contaminated animal wastes are disposed of at an approved incineration facility, by proper burial, by interment or by an alternative method approved by the Department. (Unprocessed liquid pathological waste may also be disposed of in accordance with 105 CMR 480.200(A) and tissues may be disposed of in accordance with 105 CMR 480.200(C).
E. **Sharps**

All sharps that are generated on all of Tufts locations and subsidiaries, are managed by a professional sharps management program, including worksite sharps collection containers.

All participants in the program are trained in use of the containers, what is, and is not allowed in the containers, how the full containers are collected, stored in a secure facility, and transported offsite by program workers, where the contents are first sterilized, the containers emptied sanitized and put back into circulation.

Upon treatment at the sharps container facility, the decontaminated contents are then put to a sanitary landfill.

The sharps program will be discussed in further detail later in this document.

F. **Biotechnology By-product Effluents**:

BSL3 Facilities - Tufts University and its subsidiaries does not have / do any work with BL4 agents. Any by-product effluents from BSL3 facilities, whether containing rDNA or not, is rendered non-infectious, in accordance with 105 CMR 480.150, and sterilized on site, within the BL-3 facility. In addition to the ‘primary’ killing within the suite, decontaminated parcels are then held for the time required to assure that the biological challenge was successful, thenceforth it is placed in a rigid container, sealed, labeled and collected for secondary treatment by a licensed regulated waste vendor and treated again.

BSL 1 or BSL2 facilities manage their by-product effluents that may contain RG1 or RG2 agents in compliance with the Massachusetts Uniform State Plumbing Code (248 CMR) and the Mass DEP regulations 314 CMR 7.00 (industrial wastewater permit)

8.0 Disposal (cont.)

(1) The University has an organized and functional Institutional Biosafety Committee (IBC) which is comprised of:

i. No fewer than five (5) members who collectively have experience and expertise in rDNA technology and/or RG1 and RG2 agents as needed, as well as the capacity 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

ii. At least two members, not affiliated with the institution, apart from membership on the IBC, who 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) meets once a month to evaluate the public health and environmental risks associated with all biotechnology-by-product effluents generated by the facility and determined the applicability of conditions, including appropriate effluent treatment requirements, for disposal of these wastes according to provisions of the Uniform State Plumbing Code (248);
(3) The IBC makes recommendations to management regarding the appropriate effluent
treatment requirements for facility waste at least once a year and documents those
recommendations in the required record-keeping log;
(4) IBC meetings may be open to the public; and
(5) Minutes of all IBC meetings are retained as an appendix to the required record-keeping log,
as specified in 105 CMR 480.500 (G).
9.0 Packaging, Labeling, and Shipping – 480.300

While Tufts makes every effort to perform on site decontamination of medical and biological waste, due to process of individual locations, it is sometimes more efficient to prepare waste that is to be decontaminated off site in a manner which is in compliance with the regulations. Individual locations and management plans will be discussed elsewhere in this plan. As such, the following requirements are integral to the waste management plan:

- Every container that is to be treated off-site is colored and labeled according to the requirements of 105 CMR 480.100(A)

- Each container is placed in secondary containers that are:
  - Rigid
  - Leak resistant
  - Impervious to moisture
  - Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling;
  - Sealed to prevent leakage during handling and transport

- Prior to transport for off-site disposal, or other disposal modes, 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/veterinary waste and to identify the waste generator responsible for the treatment. This waste may be disposed of in the same manner as waste that is not regulated by 105 CMR 480.000. Not including sharps.

- All shipping of medical or biological waste must comply, as applicable, with the requirements set forth in M.G.L.c. 111,§ 31A regarding permitting of waste haulers by local Boards of Health, the US Postal Service, 39 CFR part 111 and the U.S. DOT regulations, 49 CFR parts 171-180

- No containers of medical or biological/veterinary waste are shipped if there is evidence of leaking or are otherwise torn or damaged.

- Tufts and its subsidiaries do not transport any of its own waste. All forms of biological waste which must be treated off-site, including sharps, are managed by professional, licensed waste haulers.

10.0 – Shipping Papers – 480.400

-All forms of biological waste that are shipped off site for treatment are tracked through shipping papers/documents, in accordance with 105 CMR 480.400. Each generator, at each campus, location or subsidiary of the University, has an appointed designee to prepare, sign and maintain such shipping documentation.

-The documents must be signed and dated by the generator/location specific, and the following information is on the paperwork:
  - The name, address and phone number of the waste generator location, 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
  - A description of the waste being shipped
  - The total quantity of waste being shipped;
The type of container or containers used
The destination of the delivery

-Copies of all shipping papers are kept for a period of 375 days after the material is accepted by the transporter. (Or, regarding certain federal hazardous material transportation laws and regulations, for any time period therein specified). The record keeping log book for tracking the aforementioned shipping papers, are held for three years (105 CMR 480.500(H)

-The Department or the Massachusetts Board of Health may inspect the papers, upon request, at all reasonable times.

11.0 – Tracking Medical or Biological Waste for Treatment

- All Medical or Biological waste that is sent from Tufts, or one of it’s subsidiaries to treatment facilities receipt is confirmed within 30 days of shipment. Papers are matched and held for 375 days.

-Confirmation is either on paper or electronic medical waste tracking forms. These forms include shipping paper information, as well as documentation of the treatment facility’s name, address and telephone number with a contact person who has knowledge of each shipment or who has immediate access to a person who has this knowledge. The completed copy of the waste tracking form is retained with the corresponding shipping papers for a period of 375 days.

-If confirmation cannot be confirmed within 30 days after shipment, the University will report this to the Department.

12.0 – Procedures; Records; Record-Keeping Log

- As previously stated, in depth descriptions of each location’s waste management plan will be detailed in a following section. Each location plan is designed to be in compliance with the requirements listed below:

- Procedures are written, as applicable, for the decontamination of medical and biological waste to be in compliance with 105 CMR 480.000.
  ✓ Procedures to identify the types, quantities and disposition of regulated and non regulated medical or biological waste
  ✓ Protocols for safe handling and transport within the facility, if applicable from the point of generation to the point of storage and/or treatment
  ✓ A method to confirm the training of all individuals who may handle potentially infectious material waste, in the OSHA Bloodborne Pathogen Standard training.
  ✓ A listing of a contact name and emergency contact number for an individual who either has access to a person who possesses such knowledge and information
  ✓ A description of the on site regulated medical or biological waste storage areas, including those used for short-term storage. This description details the capacity of the area and the ventilation, as well as the duration that waste is maintained in each area.
- Each location that is managing medical or biological waste maintains a current record-keeping log. Each log is maintained for a period of three years and contains the following information:
  ✓ The exact date of each treatment
  ✓ The quantity of waste treated
  ✓ The type of waste
  ✓ The method of decontamination and documentation of the applicable parameters, including time, pressure, temperature, and pH.
  ✓ The printed name and signature of the person responsible for treatment
  ✓ The challenge testing/quality control (QC) analytical (growth/no growth) results and

- Each location that is shipping medical or biological waste for off-site treatment maintains a record-keeping log that contains 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 with transporter identification number
  ✓ The verification (via check box) 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.
Part II – Specific Generator Locations for Tufts University and its Subsidiaries

Tufts University - Medford Campus
A. Chemistry
B. Biology
C. Biomedical Engineering
D. Chemical Engineering
E. Physiology
F. Hooper Health Infirmary

Tufts University – Health Sciences Campus – Boston
A. Dental School
B. Medical School
C. Medical Research Facility
    a. Anatomy
    b. Biochemistry
    c. Microbiology
    d. Neuroscience
    e. Pharmacology
    f. Pathology
    g. Nutrition/Infection & Family Health
    h. Cancer Center
    i. Division of Lab Animal Medicine
D. Tufts University – USDA Human Nutrition & Research Center (HNRCA) - Boston

Tufts Cummings School of Veterinary Medicine – Grafton
A. Large Animal Hospital
B. Small Animal Hospital
C. Wildlife Studies
D. Anatomy Building
E. Administration Building
F. Peabody Pavillion – DTRR
G. Building 20 – Infectious Diseases
H. Building 21 – Infectious Diseases

Tufts University – Walpole Outpatient Clinic

Tufts University – Woodstock Ambulatory Veterinary Clinic, Woodstock, Connecticut
Part III – Plan Specific Requirements

Management of regulated waste falls into four categories,

✓ sharps,
✓ chemo waste,
✓ regulated biological waste shipped off site, and
✓ regulated biological waste decontaminated on site.

All forms of waste, regardless of type, must be rigidly controlled and kept separate from other non-regulated waste streams, to prevent accidental removal of material that must be controlled at all times prior to treatment or shipment. Temporary storage, either that awaiting off-site treatment or on site decontamination, must be in a restricted area, protected from the weather, in a well ventilated (to prevent foul odor escape), on a non-porous surface and free from vermin access. While the two regulated waste streams may be kept in the same holding area, sharps containers must be organized separately from non-sharps containers.

Sharps
✓ All locations at or within the University that generate sharps waste, are managed utilizing rigid sharps containers. Sufficient containers are provided to each generation location to properly manage the volume generated.
✓ Once containers are ¾ full, they are closed and a new container is started.
✓ Filled Containers are transported to holding facility/room awaiting pick up by the licensed vendor
✓ Appropriately completed shipping papers (manifests) are presented to the responsible person on each campus, or campus location.
✓ Shipping information is entered into a record keeping log book that contains all of the required information previously discussed.
✓ Confirmation of final disposal must be received and documented within 30 days of shipping, or the responsible person is to notify the Department (Massachusetts Department of Public Health)
✓ Shipping papers and final disposal documents must be kept for 375 days.
✓ The record keeping log must be kept for 3 years.

Chemo – Waste
✓ Chemo waste, primarily vials, syringes, etc. that may be contaminated with residual chemo waste products are placed into specifically labeled sharps containers bearing the chemo hazard symbol and different colored container than regular sharps, and managed, as above, by the same vendor managing the regular sharps containers.
✓ All manifests, confirmations, and log book requirements are the same, and this info may be entered into the same ‘record keeping log’ as the one previously mentioned.

Regulated Biological Waste Shipped off-site for Treatment
All locations within Tufts that generate regulated biological waste destined for off-site treatment are required to comply with the following:

- Waste must be placed in leak proof, red, labeled with the biohazard symbol bags that are of sufficient durability to avoid ripping or puncturing, placed within a secondary, cardboard or other rigid container which is sealed.
- Such waste must be labeled with shipper’s documentation of generator, nature of waste, and the shipper’s information and contact information.
- The shipper must complete shipping papers (manifests) and present to the person responsible for record-keeping for review and signatures.
- The responsible person will enter the required information into the specific ‘record-keeping log book’, which is kept for a period of 3 years.
- The responsible person must receive and document on the log, the final disposition of the manifested waste that was shipped out.
- Manifest/disposal papers must be kept for a period of 375 days. As mentioned above, the log books which contain all the information on the shipping papers must be kept for 3 years.

**Regulated Biological Waste Decontaminated on-site**

All locations which generate regulated biological waste, and which do on-site decontamination of same, must comply with the following rules:

- All persons who are assigned to perform decontamination of regulated biological waste must have received training on the Occupational Safety and Health Administration’s Bloodborne Pathogen Training.
- All persons as mentioned above, must also be offered, and provided free of charge, the HepB vaccination.
- All workers must be provided with adequate and appropriate personal protective equipment, including, but not limited to:
  - Safety glasses
  - Lab coats
  - Face shields (if needed)
  - High temperature, long handed, reusable safety work gloves
  - Nitrile, latex or vinyl gloves
  - Non-skid mats at or around the working end of autoclaves, if indicated
  - Emergency phone information and close location
  - Emergency eye-wash and shower facilities
- Emergency contact information for each worker must be readily available in the area where the work is done.
- All locations/departments which do on-site decontamination of regulated waste must develop SOP’s for all aspects of the operation of the unit, what to do in the event of system failure, who to notify, alternative means for waste decontamination.
- Included in the SOP, must be detailed instructions on what to do in the event of a spill or chemical release or injury. Critical contact information must be readily available to all workers

In addition, the following is also required of the process:
✓ Each bag must be clear, heavy duty plastic bearing the biohazard symbol on it, which will disappear upon autoclaving.
✓ Each bag must be “tagged” with a generator tag. These tags are available thru the EH&S office by contacting the Administrative Assistant to obtain a supply for each generator. Some areas of the University who do not use these bag tags have developed a unique tagging system which is printed within the department, but which contains the same information.
✓ The bag tags supplied by the EH&S department are perforated and have a heat sensitive strip which will change color once autoclaved. The tear off portion of the tag, is held at the autoclave facility location in an orderly manner (i.e., “envelop the week of”) for a period of three years.
✓ The information on the bag tag is entered into the record keeping log specific for the autoclave location, and the log book is kept for a period of three years.
✓ All parametric measuring information available from the autoclave operations, i.e., print out strips with time, temperature, pressure, wet or dry, etc., or circular parameter charts, must be kept for a period of three years.
✓ Routine biological spore challenge testing is required to be done, generally on a monthly basis, one test for each autoclave, each month. Records of when testing was done, and results must be entered into the record-keeping log.
✓ Any specific trouble-shooting, repairs, etc., must also be entered into the log book.
✓ Each person running the autoclave, responsible to waste stream management, must print and sign their name in the space provided, for each load of waste that is decontaminated.
✓ Once the waste has been decontaminated, it is important to assure that the identification tag is still securely fastened to the bag. This bag may then be placed into a secondary, non-transparent bag and disposed of as other, non-regulated waste.
✓ Records of all service required for each unit must be held for a period of three years.
✓ Records of all troubleshooting done for each unit must also be held, and documented on record-keeping log, for a period of three years.
✓ If an autoclave unit fails and is taken out of service, clear signs to that effect must be placed on the unit to prevent inappropriate use.
**Medical or Biological Waste Record-Keeping Log**

**ON-SITE TREATMENT**

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<th>TYPE</th>
<th>METHOD</th>
<th>TIME/PRESSURE/ TEMP/PH</th>
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# Medical or Biological Waste Record-Keeping Log

## OFF-SITE TREATMENT

**TUFTS FACILITY NAME & ADDRESS**

In accordance with M.G.L.c. 111§§ 3, 5 and 127A and 105 CMR 480.000, all generators of regulated medical or biological waste who ship same off-site for treatment, must maintain a current record-keeping log with the information found below. This log must be sequentially numbered pages in a “bound” journal. The cover of the journal book must indicate the location and name of the generator. Please enter spore test and problem resolutions on reverse side of this page, with specific date information.

| DATE | # OF CONTAINERS | TYPE | WEIGHT OR VOLUME | TRANSPORTER | TRANSPORTER ID # IF APPLICABLE | SHIPPING PAPER | TRACKING FORM | PRINTED NAME | SIGNATURE NAME |
|------|-----------------|------|-----------------|-------------|-----------------|----------------|---------------|---------------|---------------|----------------|
|      |                 |      |                 |             |                 |                |               |               |               |                |
|      |                 |      |                 |             |                 |                |               |               |               |                |
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|      |                 |      |                 |             |                 |                |               |               |               |                |
Final Discussion:

While the University has a multitude of locations where autoclaves are used, and also which generate/use sharps, a large percentage of the autoclaves in use throughout the university are used for the purpose of glassware, instrument, surgical items & dressings, i.e. for sterilization, not for decontamination.

Those parties within the umbrella of Tufts University and it’s subsidiaries who generate either sharps or regulated waste must be in compliance with the rules and guidelines set forth within this plan.

**If there are any questions, please contact the EH&S office at 617-636-3615.**

All sharps generated must be managed by the required sharps management plan, utilizing rigid, metal sharps containers which are collected regularly by a licensed vendor and treated according to law. All sharps in this program are manifested and tracked.

All regulated medical or biological waste must be managed according to the plan. There are no exceptions.

Medical or biological waste destined for off-site treatment must be handled according to the previously stated plan, packaged, labeled, and manifested via a licensed vendor.

Any site that chooses to do on-site treatment of generated medical or biological waste must contact the EH&S office for training and assessment of work process plans, record-keeping logs, biological challenges, annual maintenance of equipment, etc. There are no exceptions.

This waste management plan is put in place:

June 2009

In order that the University and its subsidiaries be in compliance with 105 Code of Massachusetts Regulations (CMR) 480

___________________________                   ____________________________
Director of Environmental Health & Safety          Date