



Docket # 1092

THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 105 CMR 480.000

CHAPTER TITLE: Minimum Requirements for the Management of Medical or Biological Waste

AGENCY: Department of Public Health

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
The purpose of these regulations is to set forth minimum requirements for the storage, treatment, disposal and transportation of medical or biological waste.

REGULATORY AUTHORITY: M.G.L. c. 94C, sec. 27A, and c. 111, secs. 3, 5, and 127A

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Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *If this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

Massachusetts Municipal Association (4/15/10)
Executive Office of Communities and Development (4/15/10)

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: 5/14/10. Comments until 5/21/10.

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: _____

For the first five years: _____

No fiscal effect: No fiscal effect expected

SMALL BUSINESS IMPACT - *State the impact of this regulation on small business. Include a description of reporting, record keeping and other compliance requirements as well as the appropriateness of performance versus design standards and whether this regulation duplicates or conflicts with any other regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

These amendments are not expected to have a significant impact on small business.

CODE OF MASSACHUSETTS REGULATIONS INDEX -

List key subjects that are relevant to this regulation:

Medical or biological waste;

Home generated sharps

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number.*

Amends 105 CMR 480.000

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: James Ball DATE: 6/9/10

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: 1159 DATE: 6/25/10

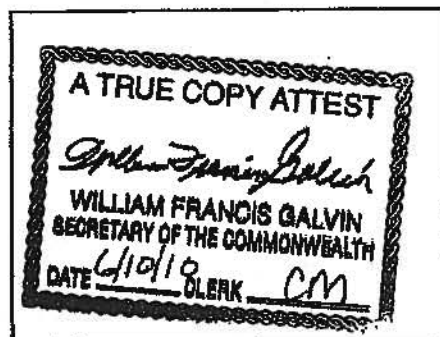
EFFECTIVE DATE: 6/25/10

CODE OF MASSACHUSETTS REGULATIONS

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2015, 2016

2015, 2016



105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 480.000: MINIMUM REQUIREMENTS FOR THE MANAGEMENT OF MEDICAL OR BIOLOGICAL WASTE (STATE SANITARY CODE CHAPTER VIII)

Section

480.001: Purpose
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480.500: Procedures; Records; Record-Keeping Log
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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.

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 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.

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

ISaATT: 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

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.

(7) 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

480.100: continued

- (6) Be maintained such that there is no putrescence of off-site odors, using refrigeration when necessary.
- (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, 2012, 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 480.12S(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

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, § 27 A, 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;
 - (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.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

480.135: continued

- (C) Operators of Sharps Collection Centers, excluding kiosks, shall comply with the requirements set forth in 105 CMR 480.100(B), (C), (O), (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 (O); 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, § 27 A 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), (O) 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, § 27 A 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), (O), (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:

- (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 1.0×10^4 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) (4) Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling; and
 - (5) (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.

- (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:

- (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;

- (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.
 - (3) 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.
 - c. 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

- (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.
 - a. 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.
 - b. 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.

- (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.