

105 CMR 480.000

MINIMUM REQUIREMENTS FOR MEDICAL OR BIOLOGICAL WASTE
(STATE SANITARY CODE CHAPTER VIII)

Deleted: STORAGE AND DISPOSAL OF INFECTIOUS OR PHYSICALLY DANGEROUS

Section

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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.

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480.002: Authority

105 CMR 480.000 is adopted under authority of M.G.L. 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 Medical or Biological Waste (State Sanitary Code Chapter VIII).

Deleted: Storage and Disposal of Infectious or Physically Dangerous

480.004: Scope

105 CMR 480.000 shall apply to all generators of medical or biological waste including home or non-commercially generated, spent hypodermic needles and lancets, but not other waste generated by residents at private dwellings.

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480.010: Definitions

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.

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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 its authorized agent or representative.

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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

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Generator: See Waste Generator

Home or Non-commercially Generated, Spent Hypodermic Needles and Lancets: All hypodermic needles and lancets that have been used or are not in their original, intact and sealed packaging and that result from personal use at a residence or outside the home. The term Home or Non-commercially Generated, Spent Hypodermic Needles and Lancets 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 and render the waste noninfectious.

Interment: Burial in a cemetery.

IStAATT: The International Society on Analytical Analysis of Treatment Technologies, 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.

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.

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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 Products shall not include: feminine hygiene products.

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(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; sputum, vomit, urine, or fecal materials that do not contain visible blood or involve confirmed diagnosis of infectious disease.

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(3) Cultures and Stocks of Infectious Agents and Associated Biologicals: All discarded cultures and stocks of infectious agents and 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:

Deleted: Human anatomical parts, organs, tissues and body fluids removed and discarded during surgery or autopsy, or other medical procedures and specimens of body fluids and their containers.

(a) Laboratories involved in basic and applied research;

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(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, and disposable razors used in connection with a medical procedure.

(6) Biotechnological By-Product Effluents: Any discarded preparations made from genetically altered living organisms and their products.

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Deleted: (d) Contaminated Animal Carcasses, Body Parts and Bedding: The contaminated carcasses and body parts and bedding of all research animals known to be exposed to pathogens.

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Deleted: Infectious or Physically Dangerous Medical or Biological Waste shall be referred to as "Waste" in the subsequent provisions of 105 CMR 480.000.¶

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 for rendering medical or biological waste non-infectious including but not limited to time, temperature, pressure and pH.

Record-Keeping Log: A log book with secured, consecutively numbered pages suitable for and which is used solely for the purpose of keeping and recording the information required by 105 CMR 480.000.

Sharps Collection Center: An identified site within a community which:

(1) uses only collection containers that meet the requirements of the federal Occupational Safety and Health Administration and the federal Department of Transportation and is marked with the international biohazard symbol;

(2) provides secure, accessible collection containers on site;

(3) accepts sharps from sharps users that are in leak-proof, rigid, puncture resistant and shatterproof containers;

(4) provides appropriate transfer containers for sharps users who fail to bring their sharps in suitable containers for placement in the collection container;

(5) has a written agreement with a medical waste transporter providing for regularly scheduled waste pickups;

(6) stores, handles, transports and treats the collected waste in accordance with 105 CMR 480.000.

(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, except generators of home or non-commercially generated, spent hypodermic needles and lancets, that generates less than 50 pounds of medical or biological waste every 180 days.

Treatment Facility: The off-site facility where medical or biological waste is rendered non-infectious 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 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 (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, physician's and dentist's offices, schools, veterinarians, funeral homes, body piercing and body art facilities, trauma scene responders and home health agencies providing services in private dwellings. It shall also include any person who produces home or non-commercially generated, spent hypodermic needles and lancets, but not other waste generated by residents at private dwellings.

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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 the requirements 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.

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480.100 Storage

(A) All medical or biological waste, except sharps, shall be contained in a primary container which is a 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, or as amended. Each primary container shall:

(1) Be marked prominently with the universal biohazard warning symbol or the word "Biohazard";

- (2) Be secured so as to prevent leakage and to preclude loss of contents during handling, storage, and/or transport; and
- (3) If the waste will be transported off-site of the waste generator for treatment:
 - (a) Be labeled in accordance with the requirements of 105 CMR 480.300(A); and
 - (b) Be placed into a secondary container in accordance with the requirements of 105 CMR 480.300(B).

(B) All areas for on-site storage of containers of medical or biological waste shall be in an uncarpeted room or area with impervious, cleanable, non-absorbent flooring, used exclusively for waste storage that 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;
- (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.

(C) Sharps shall be segregated from other wastes and aggregated in leakproof, rigid, puncture-resistant, shatterproof containers immediately after use.

(D) Free draining blood and blood products and biotechnology by-product effluents shall be stored at all times in leakproof containers that are securely sealed.

(E) 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.

(F) All medical or biological waste, except home or non-commercially generated, spent hypodermic needles and lancets, must be treated on-site or transported off-site for treatment at a minimum every 180 days.

480.125: Home or Non-commercially Generated, Spent Hypodermic Needles and Lancets

(A) Home or non-commercially generated, spent hypodermic needles and lancets, as well as unopened packages of hypodermic needles and lancets, shall be prohibited from disposal in solid municipal waste, including household waste, effective July 1, 2008 and shall be collected and disposed of in accordance with 105 CMR 480.125(B).

(B) Sharps disposal programs may include, but are not 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;

Deleted: (A) Waste generators shall contain and store medical waste at all times in leakproof, rodent proof, flytight, containers which ensure that no discharge or release of such waste occurs and that no odor or other nuisance is created.¶

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(B) All onsite storage of containers of waste shall be held in an area away from general traffic flow patterns, preferably in a room identified for this purpose. The manner of storage shall restrict access or contact with such waste to authorized persons only.¶

Deleted: (D) Wastes other than free draining blood and blood products, sharps and biotechnology by-product effluents shall be placed in a non-permeable three mil or greater polyethylene bag (or equivalent) which is securely sealed to eliminate leaks.¶

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Deleted: The following methods of treatment shall be used as appropriate:

- (3) The establishment of sharps collection centers located in municipal facilities, including, but not limited to, fire stations, police stations, senior centers and public health offices; and
- (4) Medical waste mail-back programs approved by the United States Postal Service.

(M.G.L. c. 94C, §27A)

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

(D) Upon the completion of the initial inspection the Board of Health shall notify, within 30 days, the Department and the Massachusetts Department of Environmental Protection with the location, including address, of the Sharps Collection Center(s).

(E) The Department shall maintain a list of all Sharps Collection Centers within the Commonwealth established by the Department and those reported by local health officials upon completion of the initial inspection pursuant to 105 CMR 480.125(C).

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 sterilization;
- (2) Gas sterilization;
- (3) Chemical disinfection;
- (4) Incineration at an approved incineration facility; or
- (5) 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.

- (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 International Society of Analytical Analysis of Treatment Technologies (ISaATT);
- (2) Testing methodologies including the number, type and locations shall be in accordance with procedures established 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 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, except blood saturated materials, 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) and discarded teeth and tissue may also be disposed of in accordance with 105 CMR 480.200(C).

Deleted: (a) Steam sterilization¶
(b) Gas sterilization¶
(c) Chemical disinfection¶
(d) Incineration at an approved incineration facility¶
(e) Other methods approved by the Department¶
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(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.

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(F) Biotechnology By-Product Effluents: Biotechnology by-product effluents shall not be removed from the site of the waste generator unless the viable organisms that contain recombinant DNA molecules have been rendered noninfectious in accordance with 105 CMR 480.150, except if the facility meets the below listed criteria and maintains compliance with the Massachusetts Uniform State Plumbing Code (248 CMR):

- (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, as well as the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment; 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 protection of the environment (e.g. – officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental science).
- (2) The Institutional Biosafety Committee 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 waste according to provisions of the Uniform State Plumbing Code (248 CMR); and (3) Minutes of all applicable 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 distinctively marked with the international biohazard symbol or the word "Biohazard" and colored red to indicate that it contains infectious or physically dangerous medical or biological waste.

(B) Every container or bag of waste which 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 transport.

(C) Prior to transport for off-site disposal, waste which 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 which 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.

(E) Generators shall not ship any container of medical or biological waste which shows evidence of leaking or which is otherwise torn or damaged.

(F) In the absence of any restriction concerning individuals who are authorized to transport their own waste, including but not limited to those imposed by a Board of Health or the Department of Environmental Protection, small-scale generators who transport their own waste within the Commonwealth, excluding biotechnology by-product effluents, may not transport in excess of 50 pounds every 180 days and shall follow the requirements set forth in 105 CMR 480.300, 105 CMR 480.400, 105 CMR 480.425 and 105 CMR 480.500. Producers of home or non-commercially generated, spent hypodermic needles and lancets who transport their own waste within the Commonwealth may not transport in excess of 50 pounds every 180 days and shall follow the requirements set forth in 105 CMR 480.300, but not 105 CMR 480.400, 105 CMR 480.425 and 105 CMR 480.500.

480.400: Shipping Papers

(A) Generators of medical or biological waste, including small-scale generators that transport their own waste in accordance with 105 CMR 480.300(F), and Sharps Collection Centers, but not producers of home or non-commercially generated, spent hypodermic needles and lancets, 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 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 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 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) 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) Generators, small-scale generators and Sharps Collection Centers, but not producers of home or non-commercially generated, spent hypodermic needles and lancets, 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 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 for a period of 375 days.

(B) If the generator, small-scale generator or Sharps Collection Center does not receive a hard copy or can not 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 generator, small-scale generator or Sharps Collection Center shall report this fact to the Department.

(C) Small-scale generators conducting in-state transportation of their own medical or biological waste to a separate but affiliated generator, in accordance with 105 CMR 480.300(F), shall retain the original shipping papers signed by the small-scale generator's designee and a designee from the 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 shall document all applicable information in the required record-keeping log for off-site treatment pursuant to 105 CMR 480.500(B)(2) including the term "SSG" for small-scale generator in the "ID" column and the name with address of the affiliated generator that received the material within the "transporter" column. The "shipping paper" and "tracking form" columns should be checked to reflect that both provisions have been satisfied.

(D) Generators receiving medical or biological waste from appropriate and affiliated small-scale generators, or producers of home or non-commercially generated, spent hypodermic needles and lancets, shall document all applicable information in the required record-keeping log for off-site treatment, pursuant to 105 CMR 480.500(B)(2), with a separate line dedicated to each delivery received. In addition, the term "SSG" for small-scale generator or "HNC" for home or non-commercially generated, spent hypodermic needles and lancets, which ever applies, shall be documented within the "ID" column and when applicable, the name and address of the small-scale generator shall be documented in the "transporter" column.

(1) If the medical or biological waste is to be stored and/or combined with other medical or biological waste prior to shipment for off-site treatment, the "shipping paper" and "tracking form" columns should remain blank. The next shipment for off-site treatment shall include all of the previous medical or biological waste received (SSG and/or HNC), in addition to any waste generated on-site and accounted for as a separate line item, since the last shipment. The shipping papers, as well as the medical waste tracking form, shall be itemized to indicate that all of the medical or biological waste received and any generated on-site is included in the shipment for off-site treatment.

(2) If the medical or biological waste will be rendered non-infectious on-site by the generator receiving the waste, pursuant to 105 CMR 480.150, the term "NA" for not applicable shall be documented in both the "shipping paper" and "tracking form" columns of the required record-keeping log for off-site treatment. In addition, upon treatment of the medical or biological waste, a corresponding separate line dedicated to each delivery received shall be documented in the required record-keeping log for on-site treatment including documentation of all applicable information, pursuant to 105 CMR 480.500(B)(1).

480.500: Policies and Procedures; Records; Record-Keeping Log

Generators, small-scale generators of medical or biological waste, and Sharps Collection Centers, but not producers of home or non-commercially generated, spent hypodermic needles and lancets, shall:

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

- (1) The types, quantity and disposition of regulated medical or biological waste including identification of waste approved for disposal in accordance with 105 CMR 480.200(A)(1);
- (2) The 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 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 (Appendix A and Appendix B) for all medical or biological waste 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 on its cover the name of the facility, the name of the owner and operator, if applicable, and in large print the words "Medical 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, and
 - (f) Challenge testing/quality control (QC) analytical (growth/no growth) results.
- (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 shipping identification number (if applicable),
and
 - (f) The verification of shipping papers generated with receipt of corresponding medical waste tracking forms for each shipment.

(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 the contingency plan 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 results of all analytical 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 and minutes of all meeting pursuant to 105 CMR 480.200(F)(3).

(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 transporting their own waste within the Commonwealth pursuant 105 CMR 480.400(D), for a period of 375 days.

(I) Make all such policies and procedures, records and record-keeping log 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; and

(C) 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 people 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 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 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.

(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 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.

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

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