

# SENATE NO. 673

## **AN ACT** PROTECTING THE PUBLIC HEALTH BY REFORMING THE COMMONWEALTH'S MEDICAL WASTE LAW

*Be it enacted by the Senate and House of Representatives in General Court assembled,  
And by the authority of the same, as follows:*

1 SECTION 1. The General laws are hereby amended by adding a new section: 21L. Medical Waste  
2 Treatment and Disposal.

### 3 ARTICLE I APPLICATION AND DEFINITIONS

#### 4 Section 1. Application

5 This statute applies to all persons who generate, collect, receive, store, transport, haul, treat,  
6 dispose, or handle medical waste in any form, except that this statute does not apply to individuals,  
7 such as diabetic patients, who only generate medical waste solely as a result of administering their  
8 own medical treatment.

#### 9 Section 2. Definitions

10 (a) "Biohazard bag" means a disposable red bag which is impervious to moisture and has a strength  
11 sufficient to preclude ripping, tearing, or bursting under normal conditions of usage and handling of  
12 the waste filled bag.

13 (b) "Chemotherapy waste" means waste that contains chemotherapy chemicals, or medical wastes  
14 which have been in direct contact with chemotherapy chemicals and may therefore contain small or  
15 trace quantities of chemotherapy chemicals. Chemotherapy waste does not include waste from  
16 chemotherapy units such as gloves or gowns if that waste has not been in contact with  
17 chemotherapy chemicals.

18 (c) "Container" means a biohazard bag or rigid container in which medical waste is placed.

19 (d) "Department" means the department of environmental protection.

20 (e) "Efficacy test" means proof that a treatment system can result in inactivation of vegetative  
21 bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log 10 reduction  
22 or greater; and inactivation of *B. stearothermophilus* spores and *B. subtilis* spores at a 4 Log 10  
23 reduction or greater, following a procedure specified by the Department.

24 (f) "Enforcement officer" means any agent, representative, director or employee, including  
25 environmental health specialists, of the department, or officers of a local Board of Health.

26 (g) "Household waste" means any material, including garbage, and trash which is derived from  
27 households, farms, or ranches.

28 (h) "Incineration" means any waste management mechanism that at some point in the treatment or  
29 disposal process combines heat and oxygen to burn wastes or waste byproducts. Examples of  
30 incineration include waste to energy facilities, commercial medical waste incinerators, pyrolysis,  
31 plasma arc and gasification technologies.

32 (i) "Infectious agent" means a type of microorganism, bacteria, mold, parasite, or virus which  
33 normally causes, or significantly contributes to the cause of, increased morbidity or mortality of  
34 human beings.

35 (j) "Infectious waste" means waste capable of producing an infectious disease. Infectious waste  
36 includes any of the following:

37 (1) Laboratory waste, including, but not limited to, all of the following:

38 (A) Human or animal specimen cultures from medical and pathological laboratories;

39 (B) Cultures and stocks of infectious agents from research and industrial laboratories;

40 (C) Wastes from the production of bacteria, viruses, or the use of spores, discarded live and  
41 attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures; or

42 (D) Waste containing any microbiological specimens sent to a laboratory for analysis.

43 (2) Human surgery specimens or tissues removed at surgery or autopsy, which are suspected by the  
44 attending physician and surgeon or dentist of being contaminated with infectious agents.

45 (3) Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being  
46 contaminated with infectious agents.

47 (4) Waste, which at the point of transport from the generator's site, at the point of disposal, or  
48 thereafter, contains recognizable fluid blood, fluid blood products, human body fluids, containers,  
49 or equipment containing blood that is fluid or blood from animals known to be infected with  
50 diseases which are communicable to humans.

51 5) Waste containing discarded materials contaminated with excretion, exudate, or secretions from  
52 humans who are required to be isolated by the infection control staff, the attending physician and  
53 surgeon, the attending veterinarian, or the local health officer, to protect others from highly  
54 communicable diseases or isolated animals known to be infected with diseases which are highly  
55 communicable to humans.

56 (k)(1) "Medical waste" means infectious waste or sharps waste that is generated or produced as a  
57 result of the diagnosis, treatment, or immunization of human beings or animals, or in research  
58 pertaining thereto, or in the production or testing of biologicals.

59 (2) Medical waste does not include any of the following:

60 (A) Waste containing microbiological cultures not considered to be infectious agents;

61 (B) Waste which is not infectious, such as articles containing non fluid blood, and other solid waste  
62 products such as discarded documents, food service items and other municipal trash commonly  
63 found in the facilities of medical waste generators;

64 (C) Radioactive waste;

65 (D) Household waste;

66 (E) Waste generated from normal and legal veterinarian, agricultural, and animal livestock  
67 management practices on a farm or ranch;

68 (F) Chemotherapy wastes.

69 (l) "Medical waste generator" means any person, whose acts or processes produce medical waste  
70 and includes, but is not limited to, a provider of health care. All of the following are examples of  
71 medical waste generators:

72 (1) Medical and dental offices, clinic, hospitals, surgery centers, laboratories, research laboratories.

73 (2) Veterinary establishments including offices, clinics, and hospitals, and zoos.

74 (3) "Large quantity generator" means a medical waste generator that generates 200 or more pounds  
75 per month of medical waste.

76 (4) "Small quantity generator" means a medical waste generator that generates less than 200 pounds  
77 per month of medical waste.

78 (m) "Medical waste hauler" means any person who transports medical waste. Medical waste  
79 generators who transport their own medical waste are also medical waste haulers.

80 (n) "Medical waste transfer station" means any person who receives but does not treat medical  
81 waste. Medical waste haulers who store medical waste are also medical waste transfer stations.

82 (o) "Medical waste treatment facility" means any person who treats medical waste. Medical waste  
83 generators who treat medical waste are also medical waste treatment facilities.

84 (p) "persistent bioaccumulative toxin"

85 (q) "Person" means an individual, trust, firm, joint stock company, business concern, partnership,  
86 association, or corporation, including, but not limited to, a government corporation. "Person" also  
87 includes any city, county, district, commission, the state or any department, agency, or political  
88 subdivision thereof, any interstate body, and the federal government or any department or agency  
89 thereof.

90 (r) "Sharps container" means a rigid puncture resistant container which, when sealed, is leak  
91 resistant and cannot be reopened without great difficulty.

92 (s) "Sharps waste" means any device having acute rigid corners, edges, or protuberances capable of  
93 cutting or piercing, including, but not limited to, all of the following:

94 (1) Hypodermic needles, syringes, blades, and needles with or without attached tubing; and

95 (2) Broken glass items, such as Pasteur pipettes and blood vials contaminated with medical waste.

96 (t) "Storage" means the holding of medical wastes.

97 (u) "Treatment" means any method, technique, or process designed to change the biological  
98 character or composition of any medical waste so as to eliminate its potential for causing disease.

## 99 ARTICLE 2 REQUIREMENTS APPLICABLE TO ALL PERSONS

### 100 Section 3. Segregation

101 a) All persons shall, at the point of generation and at all times thereafter, segregate medical waste  
102 from other (nonmedical) waste. No person shall mix medical waste, chemotherapy or nonmedical  
103 wastes.

104 b) Chemical wastes (mercury, formaldehyde, xylene, etc.) shall not be mixed with medical waste.

105 c) Each generator shall monitor its segregation practices periodically, and take corrective actions  
106 immediately if needed. A system of auditing and verification of the effectiveness of prevention of  
107 chemical wastes entering the regulated medical waste stream, no less than on a quarterly basis, shall  
108 be established at each generator, with documentation included as part of the facility's medical waste  
109 reduction plan.

110 d) Waste segregation policies shall be part of employee awareness and training programs.

#### 111 Section 4. Packing and handling

##### 112 (a) Solid and Semi-Solid Infectious waste

113 (1) All persons shall place solid or semi-solid infectious waste, such as animal carcasses, human  
114 body parts, and laboratory wastes in one or more red biohazard bags conspicuously labeled with the  
115 words "Infectious Waste" or with the international biohazard symbol and the word  
116 "BIOHAZARD."

117 (2) All persons shall tie biohazard bags when full to prevent leakage or expulsion of contents during  
118 handling, storage or transport.

119 (3) No person shall remove infectious wastes from a biohazard bag until after the waste is treated.

120 (4) All persons shall place biohazard bags containing infectious waste in one or more rigid  
121 containers prior to storage or transport. Rigid containers shall be leak resistant, have tight fitting  
122 covers, and be kept clean and in good repair. Containers shall be labeled with the words "Infectious

123 Waste," or with the international biohazard symbol and the word "BIOHAZARD," on the lid and on  
124 the sides so as to be visible from any direction.

125 (b) Liquid Infectious waste: All persons shall place liquid infectious waste in capped or tightly  
126 stoppered bottles, flasks or containment tanks (for large quantities of liquid waste). Such bottles,  
127 flasks or tanks shall be conspicuously labeled with the words "Infectious Waste" or with the  
128 international biohazard symbol and the word "BIOHAZARD."

129 (c) Sharps waste: All persons shall, at the point of generation and at all times thereafter, place and  
130 keep sharps waste in a sharps container. When full, sharps containers shall be taped closed or shall  
131 be tightly fastened with a lid to prevent the release of any sharps waste from the container. Sharps  
132 containers shall be labeled with the words "sharps waste" or with the international biohazard  
133 symbol and the word "BIOHAZARD." Sharps containers may be placed in biohazard bags or in  
134 containers with biohazard bags.

135 (d) All persons that generate or handle medical waste shall maintain the following ergonomic  
136 requirements:

137 (1) A policy of "no lifting" over 51 pounds.<sup>1</sup>

138 (2) Lifting devices shall be made readily available in the event that the facility periodically  
139 requires lifting of waste containers in excess of 51 pounds.

#### 140 SECTION 5. Storage

141 (a) No person shall store infectious waste above 0 degrees Centigrade for more than seven days  
142 without the written approval of the department.

143 (b) No person shall store infectious waste for more than 90 days before treatment.

144 (c) If the person is unable to control the odor from its stored waste and the odor poses a public  
145 nuisance, the department may require more frequent removal.

146 (d) All persons shall secure any area used for the storage of medical waste containers so as to deny  
147 access to unauthorized persons. Storage areas shall be marked with warning signs on, or adjacent  
148 to, the exterior of entry doors, gates, or lids. Storage areas may be secured by use of locks on entry  
149 doors, gates, or receptacle lids. Storage areas shall be maintained so as to prevent the entry of  
150 animals and natural elements and to prevent breeding places or a food source for insects or rodents.

#### 151 SECTION 6. Treatment

152 All persons treating medical wastes shall do so only by one or more of the following methods:

153 (a) Steam sterilization or other sterilization at a permitted medical waste treatment facility in  
154 accordance with all of the following standards:

155 (1) Autoclave treatment shall not be used to treat cytotoxic, hazardous or radioactive wastes, and  
156 should not be used for contaminated animal carcasses or large body parts unless the system includes  
157 an internal shredder or grinder capable of shredding such waste to a size sufficient to allow  
158 adequate penetration of heat thereby meeting the minimum level of disinfection as defined in this  
159 section.

160 (2) Written operating procedures shall be established for biological indicators, or for other  
161 indicators, of adequate sterilization approved by the department, for each steam sterilizer, including  
162 time, temperature, pressure, type of waste, type of container, closure on container, pattern of  
163 loading, water content, and maximum load quantity.

164 (3) Monitoring and Maintenance of Thermometers

165 a. Recording or indicating thermometers shall be checked during each complete cycle to  
166 ensure the attainment of at least 121 degrees Centigrade for at least one half hour,

167 depending on the quantity and density of the load, in order to achieve sterilization of the  
168 entire load.

169 b. Thermometers shall be checked for calibration quarterly.

170 c. Records of the calibration checks shall be maintained as part of the facility's files and  
171 records for a period of three years.

172 (4) Heat sensitive tape, or another method acceptable to the department, shall be used on each  
173 container that is processed to indicate the attainment of adequate sterilization conditions.

174 (5) The biological indicator *Bacillus stearothermophilus*, or other indicator of adequate sterilization  
175 as approved by the department, shall be placed at the center of a load processed under standard  
176 operating conditions at least monthly to confirm the attainment of adequate sterilization conditions.

177 (6) Records of the procedures specified in paragraphs (1), (2), and (4) shall be maintained for a  
178 period of not less than three years.

179 (7) The steam sterilization system shall comply with the efficacy tests and a performance guarantee  
180 must be provided by the supplier, before commencing operation of the unit.

181 (8) Steam sterilization shall not be used to treat contaminated animal carcasses or large body parts  
182 unless the steam sterilization system includes an internal shredder or grinder capable of shredding  
183 such waste to a size sufficient to allow adequate penetration of moist heat thereby meeting the  
184 minimum level of disinfection as defined in this section.

185 (b) Microwaving at a permitted medical waste treatment facility in accordance with all of the  
186 following standards:

187 (1) Microwave treatment shall not be used to treat cytotoxic, hazardous or radioactive wastes, and  
188 should not be used for contaminated animal carcasses or large body parts unless the system includes  
189 an internal shredder or grinder capable of shredding such waste to a size sufficient to allow

190 adequate penetration of heat thereby meeting the minimum level of disinfection as defined in this  
191 section.

192 (2) The microwave system shall comply with the efficacy test described in section (a) and a  
193 performance guarantee must be provided by the supplier before commencing operation of the unit.

194 (3) The biological indicator *Bacillus stearotherophilus*, or other indicator of adequate sterilization  
195 as approved by the department, shall be placed at the center of a load processed under standard  
196 operating conditions at least monthly to confirm the attainment of adequate sterilization conditions.

197 (4) Records of the procedures specified in paragraphs (2) and (3) shall be maintained for a period of  
198 not less than three years.

199 (c) The department of public health may approve alternative medical waste treatment methods that  
200 result in the destruction of pathogenic microorganisms without posing a risk to human health or the  
201 environment and

202 (1) the technology does not involve the incineration of waste, waste products, or treated  
203 waste;

204 (2) the technology has a proven capacity to operate without the generation or release to the  
205 environment of persistent, bioaccumulative toxics;

206 (3) the technology has been proven to meet the minimum disinfection requirement through  
207 efficacy tests done by a third party; and

208 (4) the technology minimizes hazards to worker health and safety.

209 (d) Treatment of Special Forms of Medical Waste

210 In addition to the conditions described above, treatment of the following types of wastes shall be  
211 limited to the forms of treatment prescribed in this subsection.

212 (1) Human anatomical wastes and animal wastes shall be treated with

- 213 (a) heated alkaline digestion shown to meet the efficacy test for large body parts,  
214 followed by grinding or other DPH approved method to render the treated wastes  
215 unrecognizable or
- 216 (b) steam sterilization or microwaving shown to meet the efficacy test for large body  
217 parts followed by grinding or other DPH approved method to render the treated  
218 wastes unrecognizable, or
- 219 (c) interment in accordance with the following standards:
- 220 i. A pit or trench shall be dug 2 or more meters deep. The pit or trench shall be half  
221 filled with waste, then covered with lime to within 50 centimeters of the surface before  
222 filling the rest of the pit or trench with soil.
- 223 ii. On each occasion, when wastes are added to the pit or trench, a layer of 10  
224 centimeters of soil shall be added to cover the wastes.
- 225 iii. Burial shall be closely supervised by trained personnel.
- 226 iv. It must be ensured that animals do not have any access to burial sites. Covers of  
227 concrete shall be used, although galvanized iron/wire meshes may be used if they effectively  
228 prevent access of animals.
- 229 v. Burial sites shall be relatively impermeable and not within 50 meters of any  
230 shallow well.
- 231 vi. Burial sites shall be not within 200 meters from any habitation, and sited so as to  
232 ensure that no contamination occurs of any surface water or ground water. Burial sites shall  
233 not be prone to flooding or erosion.
- 234 vii. The location of all burial sites shall be recorded and permanently maintained.

235 (2) Chemotherapy wastes, including both bulk chemotherapy wastes and wastes which have had  
236 contact with chemotherapy chemicals (trace chemotherapy wastes), shall be disposed in a RCRA  
237 Title C landfill or other non-combustion facility approved and permitted to accept the waste. The  
238 Department of Environmental Protection shall give priority to evaluating and approving alternative  
239 technologies for disposal of trace chemotherapy wastes that can prevent exposure of the public,  
240 waste management workers and the environment to the potentially harmful chemicals contained in  
241 those wastes.

242 SECTION 7. Phase-out of Medical Waste Incineration

243 (a) Emissions Limit: No person may incinerate medical waste in the state except that, prior to two  
244 years after the enactment of this statute, persons may incinerate infectious medical waste at a  
245 permitted medical waste treatment facility if it is in compliance with all of the following standards:

246	Pollutant	Limitation
247	Particulates	0.0007 gr/dscf
248	Carbon Monoxide	0.17 ppmv
249	Dioxins/Furans	0.012 ng/dscm TEQ
250	Hydrochloric Acid	0.10 ppmv
251	Sulfur Dioxide	0.85 ppmv
252	Nitrogen Oxides	42.3 ppmv
253	Lead	0.002 mg/dscm
254	Cadmium	0.0007 mg/dscm
255	Mercury	0.003 mg/dscm

256 (b) Opacity Limit

257 In addition to the above emission limits, medical/infectious waste incinerators shall be limited to no  
258 visible emissions for fugitive emissions generated during ash handling and a five percent (5%) stack  
259 opacity limit. Performance tests for fugitive emissions from ash handling must be conducted using  
260 EPA Reference Method 22. Stack opacity must be determined using EPA Reference Method 9.

261 (c) Demonstration of Continuous Compliance

262 A medical/infectious waste incinerator shall be required to demonstrate continuous compliance with  
263 the above emissions standards by doing the following:

264 (1) Each facility shall conduct on a quarterly basis a stack test for particulates, carbon monoxide,  
265 hydrochloric acid, dioxin/furan, lead, cadmium, mercury, and opacity on a quarterly basis at the  
266 expense of the medical/infectious waste incinerator owner or operator. A consultant selected and  
267 supervised by the Board of Health of the community in which the facility is situated shall conduct a  
268 review of the stack testing at the expense of the medical/infectious waste incinerator owner or  
269 operator.

270 (2) A single failure within a stack test run shall constitute failure of the test; averaging of tests  
271 shall not be permitted.

272 (3) Each facility shall conduct dioxin testing which requires three test runs of eight hours each, with  
273 a minimum of six cubic meters of stack gas collected. USEPA or California Air Resources Board  
274 procedures shall be utilized for the testing.

275 (4) The medical/infectious waste incinerator shall be tested at times when fully representative  
276 waste streams are being burned.

277 (5) The results of stack testing and of the consultant's review shall be published in a weekly  
278 newspaper of general circulation in the community in which the facility is situated, at the expense  
279 of the medical/infectious waste incinerator owner or operator.

280 (6) Each facility shall use continuous emission monitors (CEMs) for carbon monoxide,  
281 hydrochloric acid, sulfur dioxide, nitrogen oxide and oxygen. Quarterly reporting of such tests shall  
282 be required, including summaries of any exceedances.

283 SECTION 8. Disposal of treated medical waste

284 (a) All persons shall dispose of treated medical waste in a manner which does not cause releases  
285 which pose a potential to harm public health or the environment.

286 (b) Medical waste which has been effectively treated may be mixed with ordinary waste, unless  
287 the medical waste is otherwise hazardous because of its toxicity.

288 (c) No person shall dispose treated medical wastes to a solid waste incinerator or waste to  
289 energy facility, whether or not the treated wastes are solid or liquid.

290 ARTICLE 3 ADDITIONAL REQUIREMENTS APPLICABLE TO MEDICAL WASTE

291 GENERATORS

292 SECTION 9. Reporting of Audit Results

293 (a) In the event that a medical waste generator, in the course of auditing a commercial medical  
294 waste treatment, storage, transfer or disposal operation, identifies potential issues or  
295 violations relating to worker or public health and safety, the generator shall notify in writing  
296 the local Board of Health for the relevant municipality, as well as in the case of threats to the  
297 external environment, the Department of Environmental Protection, of the nature of the  
298 issues identified including the time and date of the audit. The Board of Health shall  
299 investigate the issues in question within 48 hours, or request that the Department of Public  
300 Health conduct such investigation.

301 SECTION 10. Medical Waste Reduction Plans, Progress Reports

302 (a) Within one year after enactment of this statute, each medical waste generator shall prepare a  
303 Medical Waste Reduction Plan, which evaluates ways to reduce the volume and toxicity of  
304 medical waste that is produced by the generator. The generator shall consider the quantity  
305 of waste, the hazardous properties of the waste, the safety of its patients and employees,  
306 economic costs and savings, and other appropriate factors in developing a plan. Such plan  
307 shall be integrated to the environment of care plan if such a plan is required for the facility  
308 by the Joint Committee on Accreditation of Health Care Organizations.

309 (b) At a minimum, each plan shall include:

310 (1) The scope and objectives of the plan, including evaluation of technologies, procedures, and  
311 personnel training programs that reduce unnecessary medical waste generation. The goal of the plan  
312 shall, at a minimum, be to reduce the amount of medical waste by twenty-five percent in four  
313 years, provided that the generator may set more ambitious goals, with no penalty to be provided  
314 under this or other laws for failure to attain such goals;

315 (2) Analysis of medical waste streams that identify individual processes or facilities and other  
316 activities where medical waste may be generated and identify opportunities to reduce or eliminate  
317 medical waste generation. Such assessments shall evaluate data on the types, amount, and  
318 hazardous constituents of medical waste generated, where and why that medical waste was  
319 generated, and potential medical waste reduction and recycling techniques applicable to those  
320 medical wastes;

321 (3) Employee awareness and training programs that involve employees in medical waste reduction  
322 planning and implementation to the maximum extent feasible;

323 (4) Measures to implement medical waste reduction options into management practices and  
324 procedures; and

325 (5) As part of the goal of reducing toxicity, the Medical Waste Reduction Plan shall include, among  
326 other things, measures to eliminate the inclusion of toxic materials in waste that goes to treatment,  
327 with particular focus on eliminating mercury and polyvinyl chloride wastes, and purchasing of  
328 available nontoxic alternatives to products containing toxics or toxic precursors.

329 (b) The Medical Waste Reduction Plan shall be prepared in draft and subjected to review and  
330 comment by employees of the medical waste generator and members of the public. The generator  
331 shall revise and finalize the plan to reflect the input of employees and the public.

332 (c) The department of public health shall have the authority to request a copy of the plan from any  
333 waste generator, in order to review it for compliance with the requirements this section.

334 (d) Prohibition on Certain Contract Terms. Contracts shall be prohibited for medical waste  
335 treatment, shipping, or disposal services entered after December 2, 2005 which by their terms or  
336 effect increase the effective fees charged to health care providers on a per volume, per pound, or  
337 net basis, in the event that the providers reduce the amount of waste disposed.

338 ARTICLE 4 ADDITIONAL REQUIREMENTS APPLICABLE TO PERSONS OPERATING  
339 MEDICAL WASTE TREATMENT FACILITIES

340 SECTION 11. Permits

341 (a) Any person operating a medical waste treatment facility must obtain, within 6 months after the  
342 enactment of this statute, a permit from the department of environmental protection. Such permit  
343 shall: ensure adequate controls to meet standards on emissions to water, air and land; integrate  
344 existing DEP regulatory requirements as well as the requirements of this act; and ensure that all  
345 medical waste transfer, storage, treatment and disposal facilities are regulated, as a minimum  
346 utilizing the following guidelines:

347 (1) Any permit for surface or ground water discharge, or sewer discharge, shall contain conditions  
348 on the discharge of mercury, not to exceed 1 part per billion, and to minimize or eliminate the  
349 discharge of phthalates, dioxins and persistent bioaccumulative compounds.

350 (2) Air discharges of steam or gases which may have had contact with untreated waste shall not be  
351 discharged to the air inside or outside of the facility unless they are first disinfected using steam or  
352 other method to remove pathogens. Mechanisms such as negative pressure containment devices  
353 shall be utilized to prevent such discharges.

354 (3) Monitoring shall be conducted on waste received by waste treatment facilities, prior to  
355 treatment, on one percent of closed red bag wastes to detect mercury, radiation, and volatile organic  
356 compounds. During the monitoring process such bags shall remain closed and placed in an  
357 individualized containment, to be monitored with instrumentation sensitive enough to detect traces  
358 of mercury or volatile organic compounds (VOCs) emitting from the bags.

359 (4) The treatment facility shall provide its customers with bar coded stickers coded with the unique  
360 identity of the generator facility, and which shall be adhered by the generator to all red bags, boxes  
361 or other containers shipped to the treatment facility.

362 (b) In the course of permitting, site assignment or construction of a commercial medical waste  
363 treatment or disposal facility or transfer station, the Department and DPH shall conduct a joint  
364 assessment of facility design, requesting input of members of the workforce and other affected  
365 stakeholders, which shall assess the affect of facility design on the environment and public and  
366 workforce health and safety.

367 (c) A permit shall be obtained by filing with the Department, on forms prescribed by it, an  
368 application containing all of the following information:

369 (1) The name of the applicant;

370 (2) The business address of the applicant;

371 (3) The type of treatment provided, the treatment capacity of the facility, a characterization of the  
372 waste treated at this facility, and the estimated average monthly quantity of waste treated at the  
373 facility;

374 (4) Evidence satisfactory to the department that the operator of the medical waste treatment facility  
375 has the ability to comply with the provisions of this statute;

376 (5) For an applicant who has owned or operated a facility permitted by the department, a description  
377 of all violations which occurred at any such facility in the three years prior to the date of application  
378 and stack tests, water sampling, complaints, monitoring reports, inspection records, calibration of  
379 CMI equipment and other tests of operation.

380 (6) Any other information required by the department for the administration or enforcement of this  
381 statute.

382 (d) The department shall provide timely notice to the public of all applications for a permit. The  
383 notice shall appear in local newspaper(s) and in the local language(s). The notice shall include:

384 (1) The name of the applicant;

385 (2) The business address of the applicant;

386 (3) The type of treatment provided, the treatment capacity of the facility, a characterization of the  
387 waste treated at this facility, and the estimated average monthly quantity of waste treated at the  
388 facility;

389 (4) a location where members of the public can view the permit application; and

390 (5) an address and telephone number that members of the public can use to comment on the permit  
391 application.

392 (e) The Department shall hold informational meetings prior to hearings to explain the proposed  
393 permit and its impact on the area. These meetings should be held in the vicinity of the plant or  
394 facility.

395 (f) The department shall provide 30 days after issuing notice of the permit application for the  
396 receipt of comments from the public. Any person may submit oral or written statements and data  
397 concerning the permit application. The public comment period shall automatically be extended to  
398 five days after the close of any public hearing granted under this section.

399 (g) The department shall convene a public hearing to receive comments on a permit application  
400 whenever more than five persons request one. A request for a public hearing shall be in writing and  
401 shall state the nature of the issues proposed to be raised in the hearing. Notice of a public hearing  
402 shall appear in local newspaper(s) and in the local language(s) at least 30 days before the hearing  
403 and shall contain the following information:

404 (1) The date, time, and place of the hearing;

405 (2) A brief description of the nature and purpose of the hearing; and

406 (3) A summary of major issues raised to date during the public comment period.

407 (h) Prior to issuing or renewing a permit, the Department shall review the compliance history of the  
408 applicant, under any local, state, or federal laws governing medical waste or pollution. The  
409 Department shall deny a permit, or specify additional permit conditions, if the Department  
410 determines that in the three year period preceding the date of application the applicant has violated  
411 laws or regulations governing medical waste or pollution at a facility owned or operated by the  
412 applicant and the violations demonstrate a recurring pattern of noncompliance or pose, or have  
413 posed, a significant risk to public health and safety or to the environment.

414 (i) In making a decision whether to grant or deny a permit, the Department shall consider, among  
415 other factors it considers relevant:

- 416 (1) Whether granting the permit would result in a risk of harm to the public health or the  
417 environment;
- 418 (2) The present and future ability of the applicant to safely operate the facility in compliance with  
419 all the provisions of this statute;
- 420 (3) the cumulative effects of other pollution sources within a five mile radius of the facility, and  
421 whether the community bears a disproportionate burden from such sources;
- 422 (4) the compliance history of the applicant with any local, state, or federal laws governing  
423 medical waste or pollution; and
- 424 (5) the type of treatment, including the overall performance record of the technology to be installed  
425 as shown in research studies, tests and records of enforcement agencies in other states.

426 The department shall deny the permit if it finds that:

- 427 (1) granting the permit would result in a substantial risk of harm to the public health or the  
428 environment;
- 429 (2) The applicant is not proven to be able to safely operate the facility in compliance with all the  
430 provisions of this statute when considering its capacities and compliance history;
- 431 (3) The cumulative effects of other pollution sources within a five mile radius of the facility,  
432 indicate a disproportionate burden on the community from such sources; or
- 433 (4) the type of treatment is not proven to be safe or effective.

434 (i) The Department may impose reasonable permit conditions necessary to facilitate the applicant's  
435 compliance with the provisions of this statute.

436 (j) The Department shall provide the applicant, and members of the public who commented on the  
437 application, notice of the department's decision to grant or deny a permit or to impose permit  
438 conditions. Such notice shall be in writing and include a concise statement expressing the  
439 Department's reasons for granting or denying the permit or imposing permit conditions.

440 (k) A permit shall be valid for five years. An application for renewal of the permit shall be filed  
441 with the department not less than 90 days prior to the expiration date. If a permit holder fails to  
442 make a timely application for renewal, the medical waste permit shall expire on the expiration date.

443 A permit shall terminate prior to its expiration date if either of the following occurs:

444 (1) The permit holder sells or otherwise transfers the facility, or

445 (2) The permit holder surrenders the permit to the department because the permit holder ceases  
446 operation.

447 (l) The Department may suspend, amend, or revoke any permit if the permit holder:

448 (1) Violates any provision of this statute;

449 (2) Violates any term or condition of the permit;

450 (3) Interferes with the performance of the duties of the enforcement officer;

451 (4) Intentionally makes false statements or fails to disclose fully all relevant facts, in any material  
452 regard, on an application for a permit;

453 (5) Is convicted of any crime which is substantially related to the qualifications or duties of the  
454 permit holder or which is substantially related to the functions which are subject to the permit. For  
455 purposes of this section, a conviction means a plea or verdict of guilty or a conviction following a  
456 plea of nolo contendere. An action to revoke or suspend the permit may be taken when the time for  
457 appeal has elapsed or the judgment of conviction has been affirmed on appeal. That action may  
458 also be taken when an order granting probation is made suspending the imposition of sentence. The

459 department shall take into account evidence of rehabilitation furnished by the permit holder or  
460 person in charge of the permitted activity; or

461 (6) Change any condition that requires either a temporary or permanent modification, reduction, or  
462 termination of the permitted operation to bring it into compliance with the requirements of this  
463 statute.

464 (m) The Department may temporarily suspend a permit prior to any hearing, when it has determined  
465 that this action is necessary to protect the public welfare. The department shall notify the permit  
466 holder of the temporary suspension and the effective date thereof and, at the same time, shall serve  
467 the permit holder with a notice of violation. Upon receipt of a notice of defense by the permit  
468 holder, the matter shall, within 15 days, be set for hearing. The hearing shall be held as soon as  
469 possible, but not later than 30 days after receipt of the notice. The temporary suspension shall  
470 remain in effect until the hearing is completed and the department has made a final determination  
471 on the merits. However, the temporary suspension is vacated if the department fails to make a final  
472 determination on the merits within 60 days after the original hearing has been completed.

473 (n) Any permit or compliance order issued to a treatment facility by a publicly owned treatment  
474 works shall, if it complies with the standards of this section, serve as the operative permit regarding  
475 discharge to the sewers.

476 (o) Any existing permits for facilities which fail to meet the requirements of this section shall be  
477 amended and upgraded to comply with this section within three years of the enactment of this act.

## 478 ARTICLE 5 - ENFORCEMENT

### 479 SECTION 12. Inspections

480 (a) In order to carry out the purposes of this statute, any authorized representative of the department  
481 may do any of the following:

482 (1) Enter and inspect the premises of any medical waste generator, medical waste hauler, medical  
483 waste transfer station, or medical waste treatment facility;

484 (2) Enter and inspect a vehicle of a medical waste hauler; and

485 (3) Inspect and copy any records, reports, test results, or other information related to the  
486 requirements of this statute or the regulations adopted pursuant to this statute.

487 (b) The inspection shall be made with the consent of the person or, if consent is refused, with a  
488 warrant duly issued. However, in the event of an emergency affecting the public health or safety,  
489 an inspection may be made without consent or the issuance of a warrant.

490 SECTION 13. Compliance orders, administrative penalties

491 (a) Whenever the department determines that a violation or threatened violation of this statute  
492 has resulted or is likely to result, the agency may:

493 (1) issue an order to the responsible person specifying a schedule of actions necessary for  
494 compliance, or

495 (2) require the responsible person to cease and desist generating medical waste, receiving  
496 medical waste for transport, transporting medical waste, receiving medical waste for  
497 storage, storing medical waste, receiving medical waste for treatment, or treating medical  
498 waste.

499 (b) After notice and an opportunity for hearing, the department may impose an administrative  
500 penalty of not more than ten thousand dollars (\$10,000) per violation on any person who violates an  
501 order issued pursuant to this section.

502 (c) After notice and an opportunity for hearing, the department may impose an administrative  
503 penalty of not more than one thousand dollars (\$1,000) for each day a medical waste treatment  
504 facility operates without a permit from the department.

505 SECTION 14. Civil actions

506 (a) The Department may bring an action to stop a violation, or threatened violation, of this statute in  
507 a competent court in the location in which the violation occurred or is about to occur. The  
508 Department is not required to allege facts necessary to show or tending to show the lack of an  
509 adequate remedy at law or irreparable damage or loss in any such proceedings.

510 (b) The court shall, if it finds in favor of the Department, issue an order stopping the continuance of  
511 the violation and may assess the following civil penalties:

512 (1) A penalty of not more than ten thousand dollars (\$10,000) per violation on any person who  
513 violates a provision of sections 3, 4, 5, 6, 7, 8, 10, 11, or an order issued pursuant to section 13.

514 (2) A penalty of not more than one thousand dollars (\$1,000) for each day a medical waste  
515 treatment facility operates without a permit from the department.

516 SECTION 15. Criminal liability

517 (a) Any waste hauler or treatment facility that knowingly and willfully violates any provision of this  
518 statute relating to waste treatment, hauling or transfer, or a condition of a permit held by a medical  
519 waste treatment facility, or an order of the department, is guilty of a public offense as follows:

520 (1) For a medical waste hauler, transfer station or treatment facility, a first offense is a misdemeanor  
521 punishable by a fine of not less than two thousand dollars (\$2,000), or by up to one year in jail, or  
522 by both the fine and imprisonment.

523 (2) A person who is convicted of a second or subsequent violation within three years of the prior  
524 conviction shall be punished by imprisonment for not more than three years or by a fine of not less  
525 than five thousand dollars (\$5,000) or more than twenty- five thousand dollars (\$25,000), or by both  
526 the fine and imprisonment. This section shall not apply unless any prior conviction is charged in  
527 the accusatory pleading and admitted by the defendant or found to be true by the trier of fact.

528 (3) Any person who knowingly treats or disposes, or causes the treatment or disposal of, medical  
529 waste in violation of this statute shall be punished by imprisonment of not more than three years, or  
530 by a fine of not less than five thousand dollars (\$5,000) and not more than twenty five thousand  
531 dollars (\$25,000), or by both the fine and imprisonment.

532 (4) Any person who intentionally makes any false statement or representation in any application,  
533 label, tracking document, record, report, permit, registration, or other document filed, maintained,  
534 or used for purposes of compliance with this statute is liable for a criminal penalty of not more than  
535 ten thousand dollars (\$10,000) for each separate violation or, for continuing violations, for each day  
536 that the violation continues.

537 (b) In the case of a corporation which performs commercial medical waste treatment, transfer or  
538 transportation, the knowledge held separately and collectively by each of its employees shall be  
539 considered the “knowledge” of the corporation for purposes of assessing whether the corporation  
540 “knowingly” violated any provision of this act.

#### 541 SECTION 16. Public actions

542 (a) For purposes of enforcing the provisions of this statute, any person may file an appropriate  
543 administrative, civil, or criminal action in the proper forum against:

544 (1) Any person for failure to comply with any provision of this statute, with the conditions of a  
545 permit, or with an order of the Department; or

546 (2) The department or any enforcement officer for failure to perform any act or duty under this  
547 statute that is not discretionary.

548 (b) No person may file an action until thirty days after serving notice on the person(s) against whom  
549 an action will be taken. Such notice shall inform the person(s) against whom an action will be

550 taken and the department of the nature of the actionable failures of the person, department, or  
551 enforcement officer.

552 (c) The court shall exempt public actions from the payment of filing fees. Upon prima facie  
553 showing of the failure complained of, the court shall exempt the person who filed the action from  
554 the payment of an injunction bond for the issuance of a preliminary injunction.

555 (d) The court shall, if it finds in favor of the person who filed the action, issue an order stopping the  
556 continuance of the violation and may apply the civil penalties of section 14(b)

557 (e) The court shall, if it finds in favor of the person who filed the action, award costs of litigation,  
558 including reasonable attorney and expert witness fees, to the person who filed the action. If the  
559 court finds against the person who filed the action, the court shall not award costs of litigation to the  
560 person(s) against whom the action was taken unless the action was malicious and/or baseless.

## 561 ARTICLE 6 ACCESS TO INFORMATION

### 562 Section 217. Access to records

563 (a) The department shall, in a timely manner, make available on request to any member of the  
564 public any record, report or information obtained under this statute except upon a satisfactory  
565 showing to the department by the entity concerned that the record, report or information, or parts  
566 thereof, if made public, would divulge secret methods or processes entitled to protection as  
567 intellectual property. Such records and reports include, but are not limited to, the following:

- 568 (1) Tracking documents submitted by any medical waste generator to the department;
- 569 (2) Medical Waste Reduction Plans and Progress Reports submitted to the department of Public  
570 Health by any generator;
- 571 (3) Applications for a permit and any supporting document submitted by any medical waste  
572 treatment facility to the department pursuant to section 11;

573 (4) Treatment operating records submitted by any medical waste treatment facility to the  
574 department;

575 (5) Any order issued by the department to any person pursuant to section 13.

576 The exceptions of the state public records law shall not apply to requests for these records.

577 A copy of all records generated pursuant to this relative to a treatment facility or transfer station  
578 shall be maintained at the site of operation and made available to the public upon request.

#### 579 MISCELLANEOUS ADDITIONAL PROVISIONS

##### 580 1. AMENDMENT TO STATE ZONING CODE

581 Any new commercial medical waste treatment facility or transfer station shall have a minimum of  
582 1000 foot setback from residences, schools, hospitals, prisons and other facilities commonly used  
583 for residential use or for children and from potable water supplies and at least 500 feet from  
584 waterways used for recreation or fishing.

585 Commercial medical waste facilities shall be limited to areas zoned industrially.

##### 586 2. HOST COMMUNITY FEE

587 When an application is filed for a permit pursuant to this act for a medical waste treatment facility  
588 which would accept medical waste, the applicant shall pay to the host community an assessment fee  
589 which shall be determined by the department based on the tons per day that such facility would be  
590 designed to handle. Such fee shall be calculated as follows:

591 Up to 1 ton per day: \$100,000

592 Up to 5 tons per day: \$500,000

593 Greater than 5 tons per day: \$1 million

594 The fee shall be utilized by the local Board of Health to hire technical and engineering consultants  
595 to aid in assessment of whether to issue a site assignment pursuant to MGL 150A, and the

596 conditions to be required in any such site assignment.

### 597 3. Health Care Provider Notifications

598 The Department of Public Health shall amend its regulations at 105 CMR 300 to require any  
599 physician or health care provider, no later than 10 days after detection, diagnosis or identification,  
600 to report any infectious disease which may be due to occupational exposure to medical waste.

### 601 4. AUTHORITY TO REQUIRE FINANCIAL ASSURANCE

602 The DPH, DEP or local Board of Health may in their discretion require that a commercial treatment  
603 facility establish a financial assurance mechanism to ensure that proper closure measures will be  
604 taken at the end of the facility's operational life. Such financial assurance can be provided through a  
605 trust fund, surety bond, or letter of credit. Owners or operators must maintain such financial  
606 assurance until the required closure tasks are completed, a certification of completion has been  
607 submitted to the appropriate agency, and the owner or operator has received a notification from that  
608 agency indicating that financial assurance is no longer required.