

HOUSE No. 1480

The Commonwealth of Massachusetts

PRESENTED BY:

Gloria L. Fox

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act promoting research and protecting public safety and environment.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Gloria L. Fox</i>	<i>7th Suffolk</i>	<i>2/14/2011</i>
<i>Sonia Chang-Diaz</i>		<i>2/4/2011</i>
<i>Benjamin Swan</i>	<i>11th Hampden</i>	<i>2/4/2011</i>

HOUSE No. 1480

By Ms. Fox of Boston, a petition (accompanied by bill, House, No. 1480) of Gloria L. Fox, Sonia Chang-Diaz and Benjamin Swan establishing a high containment biological research laboratory health and safety program by the Department of Public Health. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 2051 OF 2009-2010.]

The Commonwealth of Massachusetts

—————
In the Year Two Thousand Eleven
—————

An Act promoting research and protecting public safety and environment.

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. Chapter 17 of the General Laws, as appearing in the 2004 official edition is
2 hereby amended by inserting after section 17 the following:-

3 Section 18. Biological Agents Registry Program

4 Definitions. As used in this section the following words shall have the following
5 meanings:

6 “Biological agent,” any microorganism (including bacteria, virus, fungus, and protozoa),
7 or infectious substance, or any naturally occurring, bioengineered, or synthesized component of
8 any such microorganism or infectious substance, capable of causing: death, disease, or other
9 biological malfunction in a human, an animal, a plant, or another living organism; deterioration

10 of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the
11 environment.

12 “Department,” the Department of Public Health.

13 “Person,” any state, public, or private corporation or authority, any individual, trust, firm,
14 joint stock company, partnership, association, or other entity, or any group thereof, and any
15 officer, employee, or agent of such person, any group of persons, and any agency or political
16 subdivision of the Commonwealth or of the federal government.

17 “Program,” the Biological Agents Registry Program.

18 “Select Agents and Toxins” a biological agent or toxin as defined in Title 42, Part 73 of
19 the Code of Federal Regulations, Title 9, Part 121 of the Code of Federal Regulations, or Title 7,
20 Part 331 of the Code of Federal Regulations.

21 “Toxin,” any toxic material or product of plants, animals, microorganisms (including
22 bacteria, virus, fungus, rickettsiae, or protozoa), or infectious substance, or a recombinant or
23 synthesized molecule, whatever their origin and method of production, and includes: any
24 poisonous substance or biological product that may be engineered as a result of biotechnology
25 produced by a living organism; or any poisonous isomer or biological product, homolog, or
26 derivative of such a substance.

27 There is established in the department a Biological Agents Registry Program.

28 The Biological Agents Registry shall:

29

30 Identify the select agents and toxins, and other biological agents and toxins, as
31 determined by the department, possessed and maintained by any person in the Commonwealth;
32 and

33

34 Contain other information as required by regulations of the department.

35 The department shall adopt regulations for the implementation of the program that:

36

37 Determine and list the biological agents and toxins required to be reported under this
38 section, which shall include:

39 All select agents and toxins, provided that the department may exempt select agents and
40 toxins that Title 42, Part 72 or 73 of the Code of Federal Regulations, Title 9, Part 121 of the
41 Code of Federal Regulation, or Title 7, Part 331 of the Code of Federal Regulations exempt from
42 their provisions; and

43 Other biological agents and toxins as determined by the department.

44

45 Designate the persons required to make reports and the specific information required to
46 be reported;

47

48 Designate time limits for reporting, the form of reports, and the persons to whom reports
49 are to be submitted;

50

51 Require local boards of health to be informed of the location and nature of the biological
52 agents and toxins in the registry that are located within the local jurisdiction;

53 Provide for the release of information in the Biological Agents Registry to:

54 Municipal, state and federal law enforcement agencies and the Centers for Disease
55 Control and Prevention pursuant to a communicable disease or laboratory-acquired infection
56 investigation commenced or conducted by the department or municipal, state, or federal law
57 enforcement agency having investigatory authority, or in connection with any investigation
58 involving a release, spread, theft, illicit sale, or loss of biological agents;

59 The Massachusetts emergency management agency and the Massachusetts department of
60 the environmental protection for the purposes of planning for the protection of the public in
61 relation to the release of a biological agent and the prevention of a release of a biological agent;
62 and

63 The Massachusetts emergency medical services system for the purposes of providing
64 certain specified information to:

65 (A) A police officer or firefighter responding to an emergency; and

66 (B) An emergency medical services provider performing emergency services responding
67 to a fire or other emergency, or dispatched on a call for emergency services;

68 Establish a process for persons that possess and maintain select agents and toxins and
69 other biological agents and toxins to alert appropriate authorities of unauthorized possession or
70 attempted possession of such biological agents or toxins.

71 A person that possesses and maintains biological agents and toxins shall report to the
72 department the information required by the department for inclusion in the Biological Agents
73 Registry unless the department determines that the select agents and toxins, certified laboratory,
74 or facility is exempt from the requirements for the interstate shipment of etiologic agents under
75 Title 42, Part 72.6(h) or Part 72, Appendix A of the Code of Federal Regulations.

76 Information prepared for or maintained in the Biological Agents Registry shall be subject
77 to chapter 66 of the General Laws, provided that information released from the Registry is not
78 consequently a public record and a person to whom information has been released from the
79 Registry may not release the information unless such release is approved by the department.

80 A person who violates a provision of this section is guilty of a misdemeanor and on
81 conviction is subject to a fine not exceeding \$1000 for the first offense and not exceeding \$5000
82 for each subsequent conviction for a violation of the same provision. Each day a violation is
83 continued after the first conviction is a subsequent offense.

84 Section 19. High Containment Biological Research Laboratory Health and Safety
85 Program

86 Definitions. As used in this section the following words shall have the following
87 meanings:

88 “Biological agent,” any microorganism (including bacteria, virus, fungus, and protozoa),
89 or infectious substance, or any naturally occurring, bioengineered, or synthesized component of
90 any such microorganism or infectious substance, capable of causing: death, disease, or other
91 biological malfunction in a human, an animal, a plant, or another living organism; deterioration
92 of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the
93 environment.

94 “Biosafety in Microbiological and Biomedical Laboratories” or “BMBL,” a publication
95 that lists the standards and special microbiological practices, safety equipment and facilities
96 constituting Biosafety Levels 1-4, most recent edition, published by the United States
97 Department of Health and Human Services, Public Health Service, the Centers for Disease
98 Control and Prevention and the National Institutes of Health. If the publication is discontinued,
99 the most recent edition shall remain in effect as thereafter modified from time to time by
100 regulation of the department.

101 “Biosafety Level 3 laboratory” or “BSL3 laboratory,” a laboratory that is designed,
102 equipped, or operated as a biosafety level 3 laboratory as defined by the United States National
103 Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH
104 Guidelines).

105 “Biosafety Level 4 laboratory” or “BSL4 laboratory,” a laboratory that is designed,
106 equipped, or operated as a biosafety level 4 laboratory as defined by the United States National
107 Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH
108 Guidelines).

109 “Department,” the Department of Public Health.

110 “Facility,” a building or combination of buildings under common control and ownership
111 containing one or more laboratories subject to a common Institutional Biosafety Committee.

112 “High Containment Biological Research Laboratory,” a BSL3 or BSL4 laboratory.

113 “Laboratory,” a room or rooms that are used primarily for biological research,
114 development, non-routine testing, or experimentation activity, or any room or rooms where
115 vertebrate animals are contained under animal biosafety levels three and four as described in
116 NIH Guidelines/BMBL Section IV. The word “laboratory” shall also include those rooms that
117 directly serve a laboratory and are within the containment area.

118 “National Institutes of Health Guidelines” or “NIH Guidelines,” the National Institutes of
119 Health Guidelines for Research Involving Recombinant Molecules, as amended from time to
120 time. If the National Institutes of Health shall discontinue or abolish said guidelines, the most
121 recent guidelines shall remain in effect as thereafter modified from time to time by regulation by
122 the department.

123 “Person,” any state, public, or private corporation or authority, any individual, trust, firm,
124 joint stock company, partnership, association, or other entity, or any group thereof, and any
125 officer, employee, or agent of such person, any group of persons, and any agency or political
126 subdivision of the Commonwealth or of the federal government.

127 “Program,” the High Containment Biological Research Laboratory Health and Safety
128 Program.

129 “Select Agents and Toxins,” a biological agent or toxin as defined in Title 42, Part 73 of
130 the Code of Federal Regulations, Title 9, Part 121 of the Code of Federal Regulations, or Title 7,
131 Part 331 of the Code of Federal Regulations.

132 “Toxin,” any toxic material or product of plants, animals, microorganisms (including
133 bacteria, virus, fungus, rickettsiae, or protozoa), or infectious substance, or a recombinant or
134 synthesized molecule, whatever their origin and method of production, and includes: any
135 poisonous substance or biological product that may be engineered as a result of biotechnology
136 produced by a living organism; or any poisonous isomer or biological product, homolog, or
137 derivative of such a substance.

138 There is established in the department a High Containment Biological Research
139 Laboratory Health and Safety Program.

140 The program shall provide standards for the location, operation, and maintenance of high
141 containment biological research laboratories and the oversight of such laboratories to protect the
142 safety of laboratory workers, the public, and the environment from select agents and toxins.

143 The department shall adopt regulations for the implementation of the program that:

144 Set criteria for determining appropriate locations for siting a building with a BSL4
145 laboratory, including whether a BSL4 laboratory may be created within an existing building, that
146 at a minimum include that:

147 Sites shall not be within a floodplain, near a property whose regular use could
148 significantly endanger the site through fire or explosion, or near an area of high traffic
149 congestion that might impede emergency access or evacuation or endanger motorists;

150 Sites shall have sufficient land available to provide for a reasonable buffer around the
151 building, a minimum of 150 unobstructed feet in every direction;

152 Other criteria for consideration include: the proximity of flood plains, wetlands,
153 waterways, and water bodies; the relationship of the site to groundwater elevations; the nature
154 and extent of residential areas and schools through grade twelve in proximity to the site; the
155 availability and suitability of access roads to the site, including the ability of first responders to
156 access the site in an emergency; the potential for adverse public health and safety impacts; the
157 potential impact of increased traffic volume on roads to the site; and the potential threat of a
158 terrorist attack on or infiltration of the building.

159 Provide a process to determine whether to approve the siting of a new BSL4 laboratory
160 that includes:

161 An application to be completed by a person wishing to site a building with a BSL4
162 laboratory or add a BSL4 laboratory to an existing building that did not have a BSL4 laboratory;

163 The department holding a public hearing on the application in the municipality where the
164 laboratory would be located;

165 The department, the department of environmental protection, the board of health of the
166 municipality in which the facility would be located reviewing the application and approving the
167 siting if they determine that the proposed site and building would not constitute a threat to the
168 public health or safety or the environment;

169 The decision on the siting is made in writing with findings as to why the decision was
170 made;

171 The approval or denial of siting may be appealed pursuant to provisions of section
172 fourteen of chapter thirty A;

173 Require each facility with a BSL4 laboratory that has been approved as required by
174 subsection (2) to submit to the department the construction plans for the facility, construction
175 schedule, the application submitted to the National Institutes of Health (NIH), if applicable, the
176 as-built plans when completed, and documentation of third-party commissioning of the facility.

177

178 Assure that high containment biological research laboratories meet or exceed federal
179 guidelines for health and safety practices, including that:

180 Each facility with a high containment biological research laboratory complies with the
181 most current versions of the following guidelines: NIH Guidelines; BMBL; and Guidelines on
182 Primary Containment for Biohazards (Centers for Disease Control/NIH); or more protective
183 regulations that the department might adopt.

184 Each facility with a high containment biological research laboratory shall establish an
185 Institutional Biosafety Committee (IBC) in accordance with the NIH Guidelines, whether it is
186 NIH funded or not. At least two members of the IBC shall be residents of the municipality in
187 which the facility is located and shall be independent of the facility, its contractors, and
188 consultants. One such member shall be appointed by the department and the other shall be
189 appointed by the local board of health. A member appointed by the department or local board of
190 health may be rejected by the facility only for good cause.

191 An IBC shall comply with NIH Guidelines applicable to IBCs for all research in high
192 containment biological research laboratories, whether recombinant DNA research or not, and
193 may be further regulated by the department. Each IBC for a facility with high containment
194 biological research laboratory shall, at a minimum:

195 (A) Provide the department with a complete list of all members of the IBC, including
196 member's name, title, business mailing address, phone number, fax number, e-mail, and
197 curriculum vitae. The list and curriculum vitae shall be updated with any changes at least
198 annually.

199 (B) Review and approve all projects in facilities operating a high containment biological
200 research laboratory prior to the projects commencing. A protocol registration document, as
201 defined by the NIH guidelines, shall be required for all approved IBC projects with select agents
202 and toxins and other regulated agents requiring BSL3 or BSL4 containment. The documents
203 shall be sent to the department and are subject to chapter 66 of the General Laws.

204 (C) Take and keep minutes of IBC meetings that conform to the NIH Guidelines and
205 provide the minutes to the department. The minutes shall be accessible for members who do not
206 attend the meetings. The minutes shall include, but not be limited to: IBC members present at
207 the meeting; a description of any current or pending research; any comments or concerns made at
208 the meeting; and any voting, administrative matters, accident reporting or compliance issues
209 discussed. The department may provide the minutes to the local board of health upon request.

210 (D) Inspect the high containment biological research laboratories at least annually and
211 submit the results of the inspections to the department.

212 (E) Meet at least annually with a representative of the department to review safety
213 procedures, discuss health issues relating to operation of its facility, and such other issues
214 identified by the department.

215 (F) Hold at least one public meeting annually to a report on health and safety issues at the
216 facility and take public comments about the facility.

217 Require prior approval by the department for research that may or is intended to:

218 Enhance the harmful consequences of a biological agent or toxin. Harmful consequences
219 include the ability to critically alter normal biological functions, or inflict damage on public
220 health resources, materiel, and public safety. Enhancement includes augmenting properties such
221 as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin
222 to be disseminated;

223 Disrupt immunity or the effectiveness of an immunization;

224 Confer to a pathogenic agent or toxin resistance to clinically or agriculturally useful
225 prophylaxes or therapeutics against that agent or toxin;

226 Facilitate the ability of a biological agent or toxin to evade detection methodologies;

227 Increase the stability, transmissibility, or the ability to disseminate a biological agent or
228 toxin;

229 Alter the host range or tropism of a pathogenic agent or toxin;

230 Enhance the susceptibility of a host population, including by immuno-modulation of the
231 host to increase pathogenicity; or

232 Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct
233 pathogenic agent. A novel agent is an agent that has not existed previously and is considered
234 unique based on biological or other properties and traits.

235 Such approval may be granted only upon a showing that the facility has taken special
236 precautions to minimize or eliminate health and safety risks arising from such research.

237 Require each facility with a high containment biological research laboratory to complete
238 a permit application and obtain a permit from the department to operate its high containment
239 biological research laboratories. Said permits shall contain the terms and conditions the
240 department determines are necessary to protect worker and public health and safety and the
241 environment. Said permits shall not exceed five years in duration but may be renewed or
242 reissued by the department after receipt of a new completed permit application that meets
243 regulatory requirements. The department may issue or renew a permit only upon finding that no
244 condition or circumstance exists in the facility that is prejudicial to worker or public health and
245 safety or the environment. The department may suspend or revoke a permit upon finding that a
246 condition or circumstance exists in the facility that is prejudicial to worker or public health and
247 safety or the environment.

248 Require each facility with a high containment biological research laboratory to have a
249 medical surveillance plan created in consultation with a licensed physician experienced in
250 occupational health or infection control and familiar with biological laboratory exposures and
251 informed about select agents and toxins. The purpose of the plan is to establish employee and
252 researcher occupational health records, document and require inoculation for diseases when a
253 safe vaccine is available, screen for illness among laboratory workers, require reporting of

254 laboratory accidents, monitor and track releases and laboratory-acquired infections and spreads,
255 and report within the facility and to appropriate government entities. The specifics of the
256 medical surveillance and infection control protocol must meet standards established by the
257 department and be approved by the department. The medical surveillance plan shall be
258 implemented through an employee experienced in occupational health or infection control,
259 familiar with biological laboratory exposures, and informed about select agents and toxins. The
260 employee shall also:

261 Report any accidental or intentional human exposure to a pathogenic biological agent or
262 toxin, or reasonable likelihood of such exposure, to the department as soon as possible and in no
263 case more than 24 hours after learning of the exposure;

264 Report any accidental or intentional release or spread of a pathogenic biological agent or
265 toxin, or reasonable likelihood of a release or spread, outside the containment area of a BSL 3 or
266 BSL4 laboratory to the department as soon as possible, and in no case more than 24 hours after
267 the release. The report also shall be provided to the board of health in the municipality in which
268 the facility is located and any other municipality affected by the release.

269 Provide the IBC with a report of all incidents, accidents, and other events that caused or
270 are suspected to have caused a threat to the public health, death, illness, or bodily injury to any
271 person in the laboratory, as they occur, but no later than 3 days after the incident.

272 Require each facility with a high containment biological research laboratory to have and
273 implement a plan to provide adequate training for the proper handling of pathogenic biological
274 agents and toxins that might be present in the laboratory. Such training shall include, but not be
275 limited to, decontamination methods, personnel safety precautions and work habits, early

276 warning disease surveillance, and accident response actions and notifications. The facility shall
277 provide a training plan to its IBC and the department for approval and shall update the plan
278 annually, if necessary. The training plan shall ensure that all laboratory staff and researchers,
279 including the principal investigator for each facility, are trained adequately and that the principal
280 investigator participates in the creation and implementation of the training plan. No individual
281 other than a local, state or federal government representative requiring access for regulatory
282 compliance or investigative purposes may enter a high containment biological research
283 laboratory located within a facility without first completing the facility's training plan.

284 Require each facility with a high containment biological research laboratory to have and
285 implement a waste management and decontamination plan approved by the department.

286 A facility with a high containment biological research laboratory shall develop an
287 emergency response plan, in conjunction with local and state officials, that addresses security
288 threats and releases and spread of pathogenic biological agents and toxins. The emergency
289 response plan shall comply with local, state or federal plans already in existence. The plan must
290 address such events as severe weather (such as hurricanes and floods), earthquakes, power
291 outages, terrorism, and other natural, accidental, or intended disasters or emergencies. The
292 emergency response plan shall at a minimum address the following:

293 The hazards associated with the use of the select agents and toxins and special procedures
294 needed to address the hazards of specific select agents and toxins.

295 Personnel roles, lines of authority, training, and communication.

296 Emergency assessment and prevention.

297 Site security and control.

298 Evacuation routes and procedures.

299 Decontamination.

300 Emergency medical treatment and first aid.

301 Emergency alerting and response procedures.

302 Personal protective and emergency equipment.

303 Regularly scheduled preparedness exercises in coordination with local public health and
304 safety officials.

305 Critique of response and follow-up after an incident has occurred.

306 Communication to the public and news media.

307 A facility with a BSL4 laboratory shall coordinate with a hospital within a five mile
308 radius of the facility for a medical response to human exposure to a pathogenic biological agent
309 or toxin, and do so in conformity with existing public health guidelines and regulations. If there
310 is no hospital medically equipped to coordinate this type of response within a five mile radius of
311 said facility, then the coordination shall be performed at the closest hospital to the facility so
312 equipped. Said coordination shall include, but not be limited to, addressing transportation,
313 isolation, and quarantine issues as appropriate to the diseases caused by select agents and toxins
314 at the facility. If the closest hospital has created a plan in collaboration with the department
315 under the Bioterrorism Grant Program, the facility is not required to pay for the cost of annual
316 drills.

317 Every facility that has a high containment biological laboratory shall purchase property
318 and general liability insurance. The insurance shall provide compensation for harm that would be
319 caused to facility workers and the public in the event of a release of a toxin or agent or other
320 hazardous exposure to dangerous pathogens, and from damages caused by a terrorist attack on
321 the facility.

322 No employee, researcher, or student shall be required to conduct scientific research,
323 experimentation, or study or take other action in a facility with a high containment biological
324 research laboratory that violates any provision of this section or has reasonable potential to
325 adversely affect public or worker health, safety, or the environment.

326

327 A facility with a high containment biological research laboratory shall not take any
328 retaliatory action against an employee, researcher, or student in the facility because that person
329 discloses or threatens to disclose to a supervisor or a public body an activity, policy or practice
330 that the employee, researcher or student reasonably believes is in violation of this section or
331 objects to or refuses to participate in any activity, policy or practice that the employee, researcher
332 or student reasonably believes is in violation of this section.

333 The protection against retaliatory action shall not apply to the public disclosure of
334 confidential or proprietary information, trade secrets or other confidential materials unless the
335 employee, researcher or student makes such disclosure directly and exclusively to the office of
336 the attorney general or the department. The department shall not publicly disclose any such
337 confidential information, but shall submit the information to the Attorney General forthwith.

338

339 An employee, researcher or student aggrieved by a violation of this subsection may,
340 within two years, file a complaint with the attorney general, who may bring an action in the
341 name of the Commonwealth against the facility alleged to have violated this section. Provided
342 further, that within ninety days of receiving said complaint, the attorney general shall notify the
343 complainant in writing as to whether he intends to bring an action in the name of the
344 Commonwealth. If the attorney general declines to bring an action based on the complaint filed,
345 the aggrieved employee, researcher or student may, within one year, institute a civil action in the
346 superior court. Any party to said action shall be entitled to claim a jury trial. All remedies
347 available in common law tort actions shall be available to prevailing plaintiffs. These remedies
348 are in addition to any legal or equitable relief provided herein. The court may: (i) issue
349 temporary restraining orders or preliminary or permanent injunctions to restrain continued
350 violation of this section; (ii) reinstate the employee, researcher or student to the same position
351 held before the retaliatory action, or to an equivalent position; (iii) reinstate full fringe benefits
352 and seniority rights to the employee, researcher or student; (iv) compensate the employee,
353 researcher or student for three times the lost wages, benefits and other remuneration, and interest
354 thereon; and (v) order payment by the facility of reasonable costs, and attorneys' fees.

355 In any action brought by an employee, researcher or student under subsection (2), if the
356 court finds said action was without basis in law or in fact, the court may award reasonable
357 attorneys' fees and court costs to the facility. An employee, researcher or student shall not be
358 assessed attorneys' fees if, after exercising reasonable and diligent efforts after filing a suit, the
359 employee, researcher or student moves to dismiss the action against the facility, or files a notice
360 agreeing to a voluntary dismissal, within a reasonable time after determining that the facility
361 would not be found liable for damages.

362 Nothing in this subsection shall be deemed to diminish the rights, privileges or remedies
363 of any employee, researcher or student under any other federal or state law or regulation, or
364 under any collective bargaining agreement or employment contract.

365 A facility with a high containment biological research laboratory shall publicly display
366 notices designed to inform its employees, researchers and students of their protections and
367 obligations under this subsection, and use other appropriate means to keep its employees,
368 researchers or students so informed. Each notice posted pursuant to this subsection shall include
369 the name of the person or persons the facility has designated to receive written notification of a
370 suspected violation of this section.

371 A facility with a high containment biological research laboratory shall have a security
372 plan developed in coordination with state and local public safety officials. The security plan
373 shall describe the deployment of security guards; the number of guards at each facility; other
374 protective measures, including, coordination of security response with Federal, State, and Local
375 authorities; restricted personnel access to each BSL3 and BSL4 laboratory; perimeter site
376 security, internal site security, and fire protection barriers; and background security clearance for
377 employees and prospective employees. If, at any time, the department of public safety
378 determines that the security plan or implementation of the security plan for a BSL3 or BSL4
379 facility or laboratory is insufficient to ensure its security, the municipality or department of
380 public safety shall submit to the facility a report that identifies the vulnerability of the facility or
381 laboratory, and recommended actions to eliminate the vulnerability. Said recommendations or
382 other remedial actions shall be implemented by the facility immediately.

383 To ensure compliance with this section and to protect the public health and safety and the
384 environment, the department shall have the authority to review all documentation relating to the
385 operations of a high containment biological research laboratory and conduct physical inspections
386 of any such laboratory, and any other part of a facility that supports the laboratory, with or
387 without prior notice; so long as such inspections are conducted at reasonable times and in a
388 manner that maintains the health and safety systems of the laboratory.

389 A person who willfully or knowingly violates this section or a regulation promulgated
390 pursuant to this section is subject to judicially imposed criminal and civil penalties as well as
391 civil administrative penalties. Each day that a violation occurs or continues constitutes a
392 separate violation. A violation may be punished by the administrative imposition of a penalty of
393 not less than \$100 and not more than \$25,000 for each day of violation. A violation may be
394 punished by a fine not less then \$100 and not more than \$25,000, or by imprisonment for not
395 more than two years in the house of correction. Punishment imposed under this section does not
396 preclude any other penalty prescribed by law.

397 If a facility or laboratory remains in violation of this section or a regulation promulgated
398 pursuant to this section after written notice from the department without taking reasonable steps
399 to alleviate the violation, the department shall have the authority to close the facility or
400 laboratory until the violation is remedied. If the department finds that an imminent and
401 substantial threat to worker or public health or safety or the environment exists in a facility or
402 laboratory, it may request the attorney general bring suit or an action for injunctive relief.

403 Each municipality in the Commonwealth shall have the authority to regulate and prohibit
404 high containment biological research laboratories within its jurisdiction. If a municipality has a

405 regulatory program for high containment biological research laboratories that the department
406 finds is at least as protective of worker and public health and safety and environment as this
407 program, upon request of the municipality the department may certify the municipal program to
408 operate in the place of this program in the municipality.

409 SECTION 2. The Department of Public Health shall adopt regulations to implement this
410 act within one year after the effective date of this act.

411 SECTION 3. Section 19(d)(2), concerning whether to approve the siting of a new BSL4
412 laboratory, shall not apply to any building intended to include a BSL4 laboratory that has a
413 building permit and is under construction as of the effective date of this act.