

# SENATE BILL 758

J1

2lr1243

---

By: **Senators Young, Klausmeier, and Montgomery**

Introduced and read first time: February 3, 2012

Assigned to: Finance

---

## A BILL ENTITLED

1 AN ACT concerning

2 **Department of Health and Mental Hygiene – Containment Laboratories –**  
3 **Oversight**

4 FOR the purpose of establishing the Containment Laboratory Oversight Division in  
5 the Department of Health and Mental Hygiene; requiring the Division to  
6 establish and enforce certain standards and requirements relating to certain  
7 containment laboratories in the State for a certain purpose; providing that the  
8 Division shall be the sole unit of State government responsible for oversight of  
9 certain containment laboratories; requiring the Secretary of Health and Mental  
10 Hygiene to adopt certain regulations; requiring a certain facility to hold a  
11 certain license before the facility may operate a containment laboratory on or  
12 after a certain date; requiring the Secretary to set certain fees; providing for the  
13 qualifications for a license to operate a containment laboratory; requiring a  
14 certain applicant to submit an application to the Division on a certain form;  
15 specifying the contents of an application for a certain license; requiring a certain  
16 applicant to pay a certain fee to the Division; providing for the issuance,  
17 expiration, renewal, and scope of a certain license; specifying the contents of a  
18 certain license issued by the Division; authorizing the Division to deny a license  
19 to an applicant or revoke a license under certain circumstances; requiring the  
20 Division to give notice and an opportunity for a hearing to certain applicants or  
21 licensees before taking certain action; establishing the Containment Laboratory  
22 Advisory Committee to advise the Secretary on certain matters; providing for  
23 the composition and appointment of Advisory Committee members; providing  
24 for the designation of an Advisory Committee chair; establishing the terms of  
25 the appointed members of the Advisory Committee; prohibiting a member of the  
26 Advisory Committee from receiving certain compensation but authorizing the  
27 reimbursement of certain expenses; requiring the Department of Health and  
28 Mental Hygiene to provide staff for the Advisory Committee; requiring the  
29 Biological Agents Registry Program to be administered under the jurisdiction of  
30 the Division; providing for the application of this Act; defining certain terms;  
31 specifying the terms of the initial appointed members of the Advisory

---

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Committee; and generally relating to standards and oversight for containment  
2 laboratories.

3 BY repealing and reenacting, with amendments,  
4 Article – Health – General  
5 Section 17–602(a)  
6 Annotated Code of Maryland  
7 (2009 Replacement Volume and 2011 Supplement)

8 BY adding to  
9 Article – Health – General  
10 Section 17–701 through 17–712 to be under the new subtitle “Subtitle 7.  
11 Containment Laboratories”  
12 Annotated Code of Maryland  
13 (2009 Replacement Volume and 2011 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
15 MARYLAND, That the Laws of Maryland read as follows:

16 **Article – Health – General**

17 17–602.

18 (a) (1) There is a Biological Agents Registry Program in the Department.

19 (2) **THE PROGRAM SHALL BE ADMINISTERED UNDER THE**  
20 **JURISDICTION OF THE CONTAINMENT LABORATORY OVERSIGHT DIVISION IN**  
21 **THE DEPARTMENT.**

22 **SUBTITLE 7. CONTAINMENT LABORATORIES.**

23 **17–701.**

24 (A) **IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS**  
25 **INDICATED.**

26 (B) (1) **“BIOLOGICAL AGENT” MEANS ANY MICROORGANISM OR**  
27 **INFECTIOUS SUBSTANCE, OR ANY NATURALLY OCCURRING, BIOENGINEERED,**  
28 **OR SYNTHESIZED COMPONENT OF ANY MICROORGANISM OR INFECTIOUS**  
29 **SUBSTANCE, THAT IS CAPABLE OF CAUSING:**

30 (i) **DEATH OF, OR DISEASE OR OTHER BIOLOGICAL**  
31 **MALFUNCTION IN, A HUMAN, AN ANIMAL, A PLANT, OR ANOTHER LIVING**  
32 **ORGANISM;**

1                   **(II) DETERIORATION OF FOOD, WATER, EQUIPMENT,**  
2 **SUPPLIES, OR MATERIAL OF ANY KIND; OR**

3                   **(III) HARM TO THE ENVIRONMENT.**

4                   **(2) “BIOLOGICAL AGENT” INCLUDES BACTERIA, VIRUSES, FUNGI,**  
5 **AND PROTOZOA.**

6                   **(C) “BIOSAFETY LEVEL-3 LABORATORY (BSL-3)” MEANS A**  
7 **LABORATORY USED TO WORK WITH BIOLOGICAL AGENTS THAT:**

8                   **(1) ARE TRANSMITTED THROUGH THE AIR; AND**

9                   **(2) CAN CAUSE A POTENTIALLY SERIOUS OR LETHAL HUMAN**  
10 **DISEASE.**

11                   **(D) “BIOSAFETY LEVEL-4 LABORATORY (BSL-4)” MEANS A**  
12 **LABORATORY USED TO WORK WITH BIOLOGICAL AGENTS THAT:**

13                   **(1) MAY BE TRANSMITTED THROUGH THE AIR; AND**

14                   **(2) POSE A HIGH RISK OF LIFE-THREATENING OR LETHAL**  
15 **HUMAN DISEASE FOR WHICH NO VACCINE OR THERAPY IS AVAILABLE.**

16                   **(E) “CONTAINMENT LABORATORY” MEANS ANY PRIVATE OR ACADEMIC**  
17 **LABORATORY THAT QUALIFIES AS A BIOSAFETY LEVEL-3 LABORATORY OR A**  
18 **BIOSAFETY LEVEL-4 LABORATORY UNDER THIS SUBTITLE.**

19                   **(F) “DIVISION” MEANS THE CONTAINMENT LABORATORY OVERSIGHT**  
20 **DIVISION.**

21                   **(G) “FACILITY” MEANS A BUILDING OR COMBINATION OF BUILDINGS**  
22 **UNDER COMMON OWNERSHIP OR CONTROL CONTAINING ONE OR MORE**  
23 **CONTAINMENT LABORATORIES.**

24 **17-702.**

25                   **THIS SUBTITLE APPLIES TO ANY PRIVATE OR ACADEMIC CONTAINMENT**  
26 **LABORATORY IN THE STATE.**

27 **17-703.**

1           **(A) THERE IS A CONTAINMENT LABORATORY OVERSIGHT DIVISION IN**  
2 **THE DEPARTMENT.**

3           **(B) THE DIVISION SHALL ESTABLISH AND ENFORCE STANDARDS FOR**  
4 **THE LOCATION, DESIGN, MAINTENANCE, AND OPERATION OF CONTAINMENT**  
5 **LABORATORIES IN THE STATE THAT PROTECT THE HEALTH AND SAFETY OF**  
6 **LABORATORY WORKERS, THE PUBLIC, AND THE ENVIRONMENT FROM**  
7 **POTENTIALLY HARMFUL BIOLOGICAL AGENTS.**

8           **(C) THE DIVISION SHALL BE THE SOLE UNIT OF STATE GOVERNMENT**  
9 **RESPONSIBLE FOR OVERSIGHT OF CONTAINMENT LABORATORIES IN THE**  
10 **STATE.**

11 **17-704.**

12           **(A) THE SECRETARY SHALL ADOPT REGULATIONS TO IMPLEMENT THIS**  
13 **SUBTITLE.**

14           **(B) (1) THE REGULATIONS ADOPTED UNDER SUBSECTION (A) OF THIS**  
15 **SECTION SHALL:**

16                   **(I) ESTABLISH THE STANDARDS AND REQUIREMENTS FOR**  
17 **CONTAINMENT LABORATORIES NECESSARY TO PROTECT THE HEALTH AND**  
18 **SAFETY OF LABORATORY WORKERS, THE PUBLIC, AND THE ENVIRONMENT**  
19 **FROM POTENTIALLY HARMFUL BIOLOGICAL AGENTS;**

20                   **(II) INTEGRATE AND STREAMLINE UNDER THE**  
21 **JURISDICTION OF THE DIVISION ANY CONTAINMENT LABORATORY OVERSIGHT**  
22 **FUNCTIONS PERFORMED BY ANY INSTRUMENTALITY, AGENCY, OR UNIT OF**  
23 **STATE GOVERNMENT, INCLUDING THE BIOLOGICAL AGENTS REGISTRY**  
24 **PROGRAM, THE OFFICE OF LABORATORY EMERGENCY PREPAREDNESS AND**  
25 **RESPONSE, THE DIVISION OF LABOR AND INDUSTRY, AND THE DEPARTMENT**  
26 **OF THE ENVIRONMENT;**

27                   **(III) ESTABLISH REQUIREMENTS FOR LICENSURE AS A**  
28 **CONTAINMENT LABORATORY;**

29                   **(IV) DEVELOP PHYSICAL PLANT DESIGN BASIS STANDARDS**  
30 **FOR CONTAINMENT LABORATORIES WITH GUIDANCE FROM:**

31                           **1. THE CENTERS FOR DISEASE CONTROL AND**  
32 **PREVENTION;**

1                                   2.    THE    UNITED    STATES    DEPARTMENT    OF  
2    AGRICULTURE;

3                                   3.    THE    AMERICAN    SOCIETY    OF    HEATING,  
4    REFRIGERATING AND AIR-CONDITIONING ENGINEERS;

5                                   4.    THE    NATIONAL    INSTITUTE    OF    STANDARDS    AND  
6    TECHNOLOGY; AND

7                                   5.    LOCAL            CONSTRUCTION            PERMITTING  
8    JURISDICTIONS;

9                                   (v)   ESTABLISH, IN COORDINATION WITH THE MARYLAND  
10   EMERGENCY MANAGEMENT AGENCY AND LOCAL ORGANIZATIONS FOR  
11   EMERGENCY MANAGEMENT, UNIFORM EMERGENCY NOTIFICATION AND  
12   RESPONSE PROCEDURES THAT STATE AND LOCAL ORGANIZATIONS FOR  
13   EMERGENCY MANAGEMENT MUST FOLLOW DURING EMERGENCIES INVOLVING  
14   CONTAINMENT LABORATORIES;

15                                  (vi)   ESTABLISH, WITH INPUT FROM LABORATORY  
16   RESEARCHERS AT THE NATIONAL INSTITUTES OF HEALTH AND OTHER  
17   RESEARCH INSTITUTIONS IN THE STATE, STANDARD PROTOCOLS THAT  
18   CONTAINMENT LABORATORY RESEARCHERS AND STAFF MUST FOLLOW WHEN  
19   WORKING WITH BIOLOGICAL AGENTS; AND

20                                  (vii)   ESTABLISH PENALTIES FOR VIOLATIONS OF  
21   STANDARDS AND REQUIREMENTS ADOPTED BY THE SECRETARY UNDER THIS  
22   SUBTITLE.

23                                  (2)   ANY DESIGN BASIS STANDARDS FOR CONTAINMENT  
24   LABORATORIES ADOPTED BY THE SECRETARY SHALL APPLY ONLY TO NEW  
25   FACILITIES OR EXISTING FACILITIES THAT INCREASE IN SIZE BY 10% OR MORE.

26                                  (c)   TO ENSURE COMPLIANCE WITH THE STANDARDS AND  
27   REQUIREMENTS ESTABLISHED BY THE SECRETARY UNDER THIS SUBTITLE, THE  
28   DIVISION SHALL CONDUCT AN INSPECTION OF EACH FACILITY THAT APPLIES  
29   FOR A LICENSE TO OPERATE A CONTAINMENT LABORATORY AT THE TIME OF  
30   THE INITIAL APPLICATION AND AT EACH RENEWAL.

31   17-705.

32                                  THE SECRETARY SHALL SET REASONABLE FEES FOR THE ISSUANCE AND  
33   RENEWAL OF LICENSES UNDER THIS SUBTITLE.

1 **17-706.**

2 **ON OR AFTER JANUARY 1, 2014, A FACILITY SHALL HOLD A LICENSE**  
3 **ISSUED BY THE DIVISION BEFORE THE FACILITY MAY OPERATE A CONTAINMENT**  
4 **LABORATORY IN THE STATE.**

5 **17-707.**

6 **TO QUALIFY FOR A LICENSE, AN APPLICANT SHALL SATISFY THE**  
7 **DEPARTMENT THAT THE FACILITY MEETS THE STANDARDS AND**  
8 **REQUIREMENTS THAT THE SECRETARY ADOPTS UNDER THIS SUBTITLE.**

9 **17-708.**

10 **(A) AN APPLICANT FOR A LICENSE SHALL SUBMIT AN APPLICATION TO**  
11 **THE DIVISION ON A FORM THAT THE SECRETARY REQUIRES.**

12 **(B) AN APPLICATION FOR A LICENSE TO OPERATE A CONTAINMENT**  
13 **LABORATORY SHALL INCLUDE:**

14 **(1) THE NAME OF THE OPERATOR OR OWNER;**

15 **(2) THE BIOSAFETY LEVEL OF THE CONTAINMENT LABORATORY;**

16 **(3) THE BIOLOGICAL AGENTS THAT WILL BE CONTAINED IN THE**  
17 **CONTAINMENT LABORATORY; AND**

18 **(4) ANY OTHER INFORMATION THAT THE SECRETARY REQUIRES.**

19 **(C) AN APPLICANT FOR A LICENSE TO OPERATE A CONTAINMENT**  
20 **LABORATORY SHALL PAY TO THE DIVISION THE APPLICATION FEE SET BY THE**  
21 **SECRETARY.**

22 **17-709.**

23 **(A) THE DIVISION SHALL ISSUE A LICENSE TO ANY APPLICANT WHO**  
24 **MEETS THE REQUIREMENTS OF THIS SUBTITLE.**

25 **(B) THE DIVISION SHALL INCLUDE ON EACH LICENSE:**

26 **(1) THE NAME OF THE FACILITY; AND**

1           **(2) THE NAME OF THE OWNER OF THE FACILITY.**

2           **(C) WHILE IT IS EFFECTIVE, A LICENSE AUTHORIZES THE LICENSEE TO**  
3 **OPERATE A CONTAINMENT LABORATORY.**

4 **17-710.**

5           **(A) A LICENSE EXPIRES ON THE FIRST ANNIVERSARY OF ITS EFFECTIVE**  
6 **DATE, UNLESS THE LICENSE IS RENEWED FOR A 1-YEAR TERM AS PROVIDED IN**  
7 **THIS SECTION.**

8           **(B) BEFORE THE LICENSE EXPIRES, THE LICENSEE MAY RENEW A**  
9 **LICENSE FOR AN ADDITIONAL 1-YEAR TERM, IF THE LICENSEE:**

10           **(1) PAYS TO THE DIVISION THE RENEWAL FEE SET BY THE**  
11 **SECRETARY;**

12           **(2) SUBMITS TO THE DIVISION A RENEWAL APPLICATION ON THE**  
13 **FORM THAT THE SECRETARY REQUIRES; AND**

14           **(3) IS IN COMPLIANCE WITH ALL STANDARDS AND**  
15 **REQUIREMENTS ESTABLISHED BY THE SECRETARY UNDER THIS SUBTITLE.**

16           **(C) THE SECRETARY SHALL RENEW THE LICENSE OF EACH LICENSEE**  
17 **WHO MEETS THE REQUIREMENTS OF THIS SECTION.**

18 **17-711.**

19           **(A) THE DIVISION MAY DENY A LICENSE TO ANY APPLICANT OR**  
20 **SUSPEND OR REVOKE A LICENSE IF THE FACILITY FAILS TO MEET THE**  
21 **STANDARDS OR REQUIREMENTS THAT THE SECRETARY ADOPTS UNDER THIS**  
22 **SUBTITLE.**

23           **(B) EXCEPT AS OTHERWISE PROVIDED IN THE ADMINISTRATIVE**  
24 **PROCEDURE ACT, BEFORE THE DIVISION TAKES ANY ACTION UNDER THIS**  
25 **SECTION, THE DIVISION SHALL GIVE THE APPLICANT OR LICENSEE NOTICE AND**  
26 **AN OPPORTUNITY FOR A HEARING.**

27 **17-712.**

28           **(A) THE GOVERNOR SHALL ESTABLISH A CONTAINMENT LABORATORY**  
29 **ADVISORY COMMITTEE TO ADVISE THE SECRETARY ON MATTERS RELATING TO**  
30 **THE IMPLEMENTATION OF THIS SUBTITLE.**

1           **(B) THE ADVISORY COMMITTEE SHALL CONSIST OF THE FOLLOWING**  
2 **MEMBERS:**

3                   **(1) THE DIRECTOR OF THE LABORATORIES ADMINISTRATION,**  
4 **OR THE DIRECTOR'S DESIGNEE;**

5                   **(2) THE DIRECTOR OF THE OFFICE OF HEALTH CARE QUALITY,**  
6 **OR THE DIRECTOR'S DESIGNEE; AND**

7                   **(3) THE FOLLOWING MEMBERS APPOINTED BY THE GOVERNOR:**

8                           **(I) ONE REPRESENTATIVE OF THE BIOLOGICAL AGENTS**  
9 **REGISTRY PROGRAM;**

10                           **(II) ONE REPRESENTATIVE OF THE OFFICE OF**  
11 **LABORATORY EMERGENCY PREPAREDNESS AND RESPONSE;**

12                           **(III) ONE REPRESENTATIVE OF THE DIVISION OF LABOR**  
13 **AND INDUSTRY, OFFICE OF SAFETY AND HEALTH;**

14                           **(IV) ONE REPRESENTATIVE OF THE DEPARTMENT OF THE**  
15 **ENVIRONMENT;**

16                           **(V) ONE REPRESENTATIVE OF THE MARYLAND**  
17 **EMERGENCY MANAGEMENT AGENCY;**

18                           **(VI) THREE REPRESENTATIVES OF A CONTAINMENT**  
19 **LABORATORY IN THE STATE, INCLUDING:**

20                                   **1. TWO REPRESENTATIVES FROM A PRIVATE**  
21 **CONTAINMENT LABORATORY; AND**

22                                   **2. ONE REPRESENTATIVE FROM AN ACADEMIC**  
23 **CONTAINMENT LABORATORY; AND**

24                           **(VII) TWO MEMBERS OF THE GENERAL PUBLIC WHO LIVE IN**  
25 **COUNTIES WHERE PRIVATE CONTAINMENT LABORATORIES OPERATE.**

26           **(C) THE GOVERNOR MAY APPOINT ANY OTHER INDIVIDUAL AT THE**  
27 **GOVERNOR'S DISCRETION.**

28           **(D) (1) THE TERM OF AN APPOINTED MEMBER IS 3 YEARS.**



1           **(2) THE TERMS OF MEMBERS ARE STAGGERED AS REQUIRED BY**  
2 **THE TERMS PROVIDED FOR MEMBERS ON OCTOBER 1, 2012.**

3           **(E) THE GOVERNOR SHALL DESIGNATE THE CHAIR OF THE ADVISORY**  
4 **COMMITTEE.**

5           **(F) A MAJORITY OF THE MEMBERS SERVING ON THE ADVISORY**  
6 **COMMITTEE REPRESENTS A QUORUM TO CONDUCT BUSINESS.**

7           **(G) A MEMBER OF THE ADVISORY COMMITTEE:**

8                   **(1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE**  
9 **ADVISORY COMMITTEE; BUT**

10                   **(2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE**  
11 **STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE**  
12 **BUDGET.**

13           **(H) THE DEPARTMENT SHALL PROVIDE STAFF FOR THE ADVISORY**  
14 **COMMITTEE.**

15           SECTION 2. AND BE IT FURTHER ENACTED, That the terms of the initial  
16 appointed members of the Containment Laboratory Advisory Committee, established  
17 under Section 1 of this Act, shall expire as follows:

18                   (1) three members in 2013;

19                   (2) three members in 2014; and

20                   (3) four members in 2015.

21           SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect  
22 October 1, 2012.