



**Department of Health and Mental Hygiene
Board of Health**

**Notice of Public Hearing and Opportunity to Comment
on Proposed Amendments to the New York City Health Code**

What are we proposing? The Department of Health and Mental Hygiene is proposing that the Board of Health amend Article 13 of the New York City Health Code, requiring non-clinical laboratories that work with certain biological agents to register with the Department and to report incidents involving the loss, theft, unintentional release or exposure to such agents.

When and where is the hearing? The Department will hold a public hearing on the proposed Health Code amendments on April 26, 2016 at 9:30AM to 11:30AM at

New York City Department of Health and Mental Hygiene
Gotham Center
42-09 28th Street, 3rd floor, Room 3-32
Long Island City, NY 11101-4132

How do I comment on the proposed amendments to the Health Code? Anyone can comment on the proposed amendments by:

- **Website.** You can submit comments to the Department through the NYC rules Web site at <http://rules.cityofnewyork.us/>
- **Email.** You can email written comments to resolutioncomments@health.nyc.gov
- **Mail.** You can mail written comments to
New York City Department of Health and Mental Hygiene
Gotham Center, 42-09 28th Street, CN 31
Long Island City, NY 11101-4132
- **Fax.** You can fax written comments to New York City Department of Health and Mental Hygiene at 347-396-6088
- **Speaking at the hearing.** Anyone who wants to comment on the proposed amendments at the public hearing must sign up to speak. You can sign up before the hearing by calling Svetlana Burdeynik at 347-396-6078. You can also sign up in the hearing room before or during the hearing on April 26, 2016. You can speak for up to five minutes.

Is there a deadline to submit written comments? Written comments must be received on or before 5:00 p.m. on April 26, 2016.

Do you need assistance to participate in the hearing? You must tell us if you need a reasonable accommodation of a disability at the hearing. You must tell us if you need a sign language interpreter.

You can tell us by mail at the address given above. You may also tell us by telephone at 347-396-6078. You must tell us by April 12, 2016.

Can I review the comments made on the proposed amendments? You may review the comments made online at <http://rules.cityofnewyork.us/> on the proposed amendments by going to the website at <http://rules.cityofnewyork.us/>. All written comments and a summary of the oral comments received by the Department will be made available to the public within a reasonable period of time by the Department's Office of the General Counsel.

What authorizes the Board of Health to make these amendments? Section 558 of the City Charter authorizes the Board of Health to adopt and amend the Health Code and to include in the Health Code all matters to which the authority of the Department extends. Section 556 of the Charter authorizes the Department to supervise matters affecting public health, including the reporting and control of diseases and conditions hazardous to life and health. This proposed amendment was not included in the Department's regulatory agenda for this Fiscal Year because it was not deemed necessary until after the agenda was published.

Where can I find the Health Code and the Department's rules? The Health Code and the rules of the Department of Health and Mental Hygiene are in title 24 of the Rules of the City of New York.

What rules govern the rulemaking process? The Board of Health must meet the requirements of §1043 of the City Charter when creating or changing the Health Code. This notice is made according to the requirements of City Charter §1043.

Statement of Basis and Purpose

Background

The Charter provides the Department of Health and Mental Hygiene (the Department) with jurisdiction over all matters concerning health in the City of New York. The Department conducts disease surveillance and control activities for diseases reportable pursuant to Article 11 of the New York City Health Code (Health Code). The Department is also required to comply with various provisions of Part 2 of the New York State Sanitary Code, found in Title 10 of the Codes, Rules and Regulations of the State of New York (NYCRR), with respect to control of communicable diseases.

“High containment research laboratories” are facilities that store and handle infectious microorganisms or hazardous biological material and operate at biosafety level (BSL) 3 or 4, as defined by the US Centers for Disease Control and Prevention (CDC) and National Institutes for Health (NIH), in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), which delineates four BSLs based on the potential risks of working with infectious or hazardous agents.

Biosafety level 1 (BSL-1) is the basic level of protection and is appropriate for agents that are not known to cause disease in normal, healthy humans. Biosafety level 2 (BSL-2) is appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure. Biosafety level 3 (BSL-3) is appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin.

Exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available are restricted to high containment laboratories that meet biosafety level 4 (BSL-4) standards.¹

Since 2001, hundreds of new high-containment research laboratories have been established in the United States. According to the U.S. Government Accountability Office (GAO), 1,495 BSL-3 and BSL-4 laboratories were registered with the Federal Select Agent Program (FSAP) in 2010 compared to 415 in 2004. This was considered an under-estimate, because it only addressed laboratories required to register with the FSAP.² With respect to those operating in New York City, the Department does not know when such facilities were or are being established, the total number operating in the City at any time, and the hazardous agents they store or handle.

Recent laboratory accidents, none of which occurred in New York City, have focused the Department's attention on this issue. In June and July 2014, CDC disclosed two potentially serious incidents involving H5N1 avian influenza³ and *Bacillus anthracis*,⁴ the bacterium that causes anthrax. A third incident at CDC involving an Ebola virus sample occurred in December 2014.⁵ In 2007, another potentially serious incident occurred at CDC when the main and backup power supplies failed during a lightning storm, shutting down the negative pressure system in a newly constructed, but not yet operational, BSL-4 laboratory.⁶

Two incidents in the past two years involving high-containment laboratories further demonstrate the potential public health risks stemming from research conducted in BSL-3 and BSL-4 laboratories. In November 2014, two primates in the Tulane National Primate Research Center were diagnosed with melioidosis, a severe disease of animals and humans caused by a potential biological threat agent, *Burkholderia pseudomallei*. The strain infecting the animals was identical to the strain used in a Tulane University laboratory registered with the FSAP. In March 2015, CDC and the U.S. Department of

¹ CDC (US) and NIH (US). Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington (DC): Centers for Disease Control and Prevention (US) and National Institutes of Health (US). 2007; 409 p. Available from <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>

² GAO (US). High-Containment Laboratories: Assessment of the Nation's Need is Missing. Washington (DC): Government Accountability Office (US). 2013 Feb 25; 13 p. Report No.: GAO-13-466R. Available from <http://www.gao.gov/products/GAO-13-466R>

³ CDC (US). Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1. 2014 August 15. <http://www.cdc.gov/about/pdf/lab-safety/investigationcdch5n1contaminationeventaugust15.pdf>

⁴ CDC (US). Report on the Potential Exposure to Anthrax. 2014 July 11. http://www.cdc.gov/about/pdf/lab-safety/Final_Anthrax_Report.pdf

⁵ CDC (US). Report on the Potential Exposure to Ebola Virus. 2015 February 4. <http://www.cdc.gov/about/pdf/lab-safety/investigation-into-dec-22-2014-cdc-ebola-event.pdf>

⁶ Government Accountability Office (US). High Containment Laboratories—National Strategy for Oversight is Needed. Washington (DC): Government Accountability Office (US); 2009 Sep. 99 p. Report No.: GAO-09-574. Available from <http://www.gao.gov/products/GAO-09-574>

Agriculture's (USDA) Animal Plant Health Inspection Service (APHIS) concluded that a number of biosafety deficiencies could have led to transmission of *B. pseudomallei* from the laboratory to the animals in the primate center.⁷

In May 2015, CDC started an investigation of a report that a U.S. Department of Defense high-containment laboratory might have inadvertently shipped live *B. anthracis* spores (the causative agent of anthrax) to a laboratory that was anticipating only deactivated spores. Ultimately, CDC concluded that this laboratory unknowingly shipped live *B. anthracis* spores on 575 separate occasions to laboratories worldwide over the course of a decade.⁸

As serious as these incidents have been, of even greater concern have been laboratory incidents over past decades that have caused outbreaks of contagious virus diseases, including smallpox, SARS, and foot and mouth disease.⁹ The Department is concerned that an accident in a NYC-based high-containment research laboratory could have catastrophic consequences, given the population density of nearly 70,000 per square mile in Manhattan and the many other areas of high population density throughout the City.

Work performed in a BSL-3 or BSL-4 facility would present the greatest potential risk to public health if an incident occurs. Research laboratories that handle biological agents and toxins and hold government contracts or grants are required to adhere to the BMBL. Most, but not all, of the agents that are stored and handled in high-containment research laboratories and that represent potential public health risks are regulated by the FSAP. Federal regulations require reporting of certain incidents involving select agents to the CDC and local, state and federal law enforcement agencies only; timely notification to local public health authorities of these incidents is not always required by the federal regulations. Federal agencies are also constrained from disclosing to local or state health departments which laboratories within a local jurisdiction are registered to handle and work with select agents. The Department has been informed by the CDC that, with the proper safeguards, information identifying the registered laboratories can be made available to the Department. However, no other information about these laboratories or the biological agents they work with would be regularly available from CDC.

Several federal agencies exercise varying degrees of oversight over academic and private high-containment research laboratories. CDC and USDA APHIS regulate laboratories working with certain biological agents and toxins that have the potential to pose a severe threat to public health and safety, known as "select agents," pursuant to 42 CFR Part 73 (CDC regulations), and 9 CFR Part 121 and 7 CFR Part 331 (USDA regulations).

⁷ CDC (US). Conclusion of select agent inquiry into Burkholderia pseudomallei release at Tulane National Primate Research Center. 2015 Mar 13. Available from <http://www.cdc.gov/media/releases/2015/s0313-burkholderia-pseudomallei.html>

⁸ HHS (US). Testimony of Daniel M. Sosin, MD, MPH, FACP, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. Review of Department of Defense Anthrax Specimens. 2015 Jul 28. Available from <http://docs.house.gov/meetings/IF/IF02/20150728/103816/HHRG-114-IF02-Wstate-SosinD-20150728.pdf>

⁹ Furmanski M. Threatened pandemics and laboratory escapes: self-fulfilling prophecies. Bulletin of the Atomic Scientists. 2014 Mar 31. Available from <http://thebulletin.org/threatened-pandemics-and-laboratory-escapes-self-fulfilling-prophecies7016>

According to the GAO, “While some federal agencies do have a mission to track a subset of BSL-3 and -4 laboratories that work with select agents and know the number of those laboratories, no single regulatory agency has specific responsibility for biosafety in all high-containment laboratories in the United States.”⁶ If a laboratory is not working with a select agent or not operating with government funding or under a government contract, it is not bound by the federal regulatory scheme, and, unless there is applicable state or local law, a laboratory may be totally unregulated.

Because of this regulatory structure, the Department does not have a means to know the number of high-containment research laboratories operating in New York City, their location, or the potentially hazardous biological agents that are stored and/or handled within them. Although clinical laboratories hold permits issued by the State Department of Health,¹⁰ non-clinical research laboratories storing and/or handling biological agents are not currently regulated by the City or State. They do not currently need to hold permits, to notify local authorities of their existence, or to report incidents of public health concern to the Department, such as loss or theft of agents or suspected transmission of diseases caused by agents stored and/or handled in the laboratories. Unless high-containment research laboratories are required to register with the Department, pre-event planning between the Department and laboratories to mitigate the public health risks and to protect public health cannot take place.

Several state and local US jurisdictions currently regulate research laboratories working with biological agents. In 1996, Connecticut, which had already required all laboratories to register and be inspected before conducting any examination, determination, or test, enacted additional reporting requirements specifically applicable to BSL-3 laboratories, requiring reporting of any infection or injury relating to work with such agents or resulting in recommendations that employees or members of the public be tested or monitored for potential public health problems.¹¹ Since 2002, Maryland has had a Biological Agent Registration Program, which is nearly identical to the FSAP. The Boston Public Health Commission adopted its Biological Laboratory Regulations in 2006. These regulations establish operational biosafety requirements and require permitting, inspections and reporting of human exposures and other incidents to the Commission. In 2009, Cambridge, Massachusetts adopted biosafety laboratory regulations and formed the Cambridge Biosafety Committee to enforce them.

The Department proposes that the Board amend Article 13 to require registration of and reporting by research laboratories that have BSL-3 and BSL-4 facilities. A registration form will require identification and contact information of owners, operators, and other persons responsible for biosafety and a list of the biological agents stored and/or handled onsite. The amendment will also require immediate reporting by such facilities to the Department of any exposures of persons, losses, thefts, or unintentional releases of such agents so that the Department can, if necessary, investigate and limit public health risks from these agents. Laboratories that are currently operating solely as clinical laboratories, blood and tissue banks and those that conduct recombinant DNA experiments pursuant to Title 5 of Article 5, or Articles 43-B or 32-A, of the New York Public Health Law would be excluded from these registration and reporting requirements.

¹⁰ See, e.g., New York Public Health Law Article 5-Laboratories.

¹¹ CONN. GEN. STAT. §19a-31a; CONN. AGENCIES REGS. §§ 19a-36-A1 to A56.

Statutory Authority

These amendments to the Health Code are promulgated pursuant to §§558 and 1043 of the Charter. Sections 558(b) and (c) of the Charter empower the Board to amend the Health Code and to include in the Health Code all matters to which the authority of the Department extends. Section 1043 grants the Department rule-making authority. Section 556(c)(2) of the Charter authorizes the Department to “supervise the reporting and control of communicable and chronic disease and conditions hazardous to life and health...”

The proposal is as follows:

“Shall” and “must” denote mandatory requirements and may be used interchangeably unless otherwise specified or unless the context clearly indicates otherwise.

New material is underlined.

[Deleted material is in brackets.]

RESOLVED, that Section 13.01 of the New York City Health Code, set forth in Title 24 of the Rules of New York City is amended, to be printed together with explanatory notes, effective 180 days after adoption, to read as follows:

§13.01 [Definition] Definitions.

When used in this article [“laboratory”]:

(a) “Laboratory” or “clinical laboratory” [shall mean] means a facility, including a blood bank, regulated pursuant to Title 5 of Article 5 of the Public Health Law[, Title V, Article 5,] holding a permit issued by the New York State Department of Health, and operating in the City or testing a specimen taken from a City resident.

(b) “Research laboratory” means a facility used primarily for research, development, storage, examination or testing of one or more biological agents by or under the direct supervision of a technically qualified individual, but does not include: (i) clinical laboratories and blood banks holding permits issued pursuant to Title 5 of Article 5 of the Public Health Law; (ii) laboratories where recombinant DNA experiments are conducted pursuant to Article 32-A of the Public Health Law; (iii) tissue or organ banks holding permits issued pursuant to Article 43-B of the Public Health Law; and (iv) laboratory facilities operated by New York State or federal governments.

(c) “Biological agent” means an infectious microorganism or hazardous biological material, such as a bacterium, virus, fungus, parasite, or biological toxin that is associated with human or animal disease.

(d) “High-containment research laboratory” means any research laboratory that operates a biosafety level 3 or biosafety level 4 facility, as defined by the Centers for Disease Control and Prevention and National Institutes for Health in *Biosafety in Microbiological and Biomedical Laboratories*, or successor document available at <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>.

Notes: Section 13.01 was amended by resolution adopted by the Board of Health at its meeting on XXX, to be effective 180 days after adoption, to add definitions applicable to certain high-containment research laboratories.

RESOLVED, that Article 13 of the New York City Health Code, set forth in Title 24 of the Rules of New York City, is hereby amended, to add new sections 13.11 and 13.13, effective 180 days after adoption, to be printed together with explanatory notes, to read as follows:

§13.11 High-containment research laboratories: registration.

(a) *Registration.* Every person operating a high-containment research laboratory in the City of New York must register such laboratory with the Department. Registrations will expire and must be renewed every two years. An entity or person registering with the Department must provide all the information requested by the Department on the registration form, including but not limited to:

(1) Name, address and other contact information for the officers or persons in control of the operating entity;

(2) Locations and biosafety level rating or ratings for each research laboratory operated by the registering entity;

(3) Name, title and contact information of at least two designated persons who are individuals at the research laboratory designated to submit to the Department the reports required by §13.13 of this Article, provided that one such designated person is the manager or other person in control of the research laboratory biosafety committee; and

(4) A listing of all biological agents kept or used in each high-containment research laboratory.

(b) *New facilities.* Any person intending to operate a new high-containment research laboratory must register such laboratory according to this section before such laboratory commences operation.

(c) *Changes in registration information.* The registrant must notify the Department within thirty (30) calendar days of any changes to the information provided on the registration form.

Notes: Section 13.11 was added to Article 13 by resolution adopted by the Board of Health at its meeting on XXX to be effective 180 days after adoption, to require registration by high-containment research laboratories keeping or working with certain biological agents that pose a risk to public health. High-

containment research laboratories in operation on the effective date of the resolution must register with the Department no later than one hundred eighty (180) calendar days after the effective date.

§13.13 High-containment research laboratories; required reports.

(a) Loss or theft of a biological agent. Within one hour of discovering the theft or loss of a biological agent from a high-containment research laboratory, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of such theft or loss at a telephone number designated by the Department. Any theft or loss must be reported even if the lost or stolen biological agent is subsequently recovered and/or the responsible parties are identified. The following information must be provided:

- (1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);
- (2) The quantity or an estimate of the quantity of the biological agent that was lost or stolen;
- (3) The time or an estimate of the time during which the theft or loss occurred;
- (4) The location (building, room) from which the theft or loss occurred.

(b) Exposure to or unintentional release of biological agents. Within one hour of discovering that a person may have been exposed to any biological agent maintained in or by a high-containment research laboratory, or of any unintentional release of a biological agent, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of the actual or potential exposure at a telephone number designated by the Department. The following information must be provided:

- (1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);
- (2) An estimate of the number of persons potentially exposed to the biological agent in or by the research laboratory and within the entity;
- (3) An estimate of the quantity of biological agent that was released;
- (4) An estimate of the time and duration of the release of the biological agent;
- (5) The environment into which the biological agent was released (e.g., within vs. outside building, into a waste system);
- (6) The location (building, room) from which the release of the biological agent occurred;
- (7) Identification and contact information for all persons known to be exposed to the biological agent;
- (8) Actions taken to respond to the release of the biological agent; and

(9) Hazards posed by the release of the biological agent.

(c) No requirement of this section affects any other obligation under any other law or regulation for a high-containment laboratory to report the loss, theft or release of a biological agent to any other law enforcement or regulatory agency.

Notes: Section 13.13 was added to Article 13 by resolution of the Board of Health adopted at its meeting on XXX, to be effective 180 days after adoption. The section requires reporting of incidents involving theft, loss, release of certain biological agents or exposure of persons to such agents.

RESOLVED, that the list of section titles in Article 13 of the New York City Health Code be, and the same hereby is, amended to be effective 180 days after adoption of this resolution, to be printed together with explanatory notes to read as follows:

ARTICLE 13
LABORATORIES

§13.01 [Definition] Definitions.

§13.03 Report of positive findings.

§13.05 Testing for tuberculosis.

§13.07 Reporting of Hemoglobin A1C.

§13.09 Neonatal herpes simplex specimens.

§13.11 High-containment research laboratories; registration.

§13.13 High-containment research laboratories; required reports.

Notes: Article 13 was amended by resolution of the Board of Health adopted at its meeting on XXX, to be effective 180 days after adoption of the resolution, to add new sections 13.11 and 13.13, requiring registration of high-containment research laboratories that work with certain biological agents and reporting of incidents involving loss or theft of, or exposures to such agents.

**NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS
253 BROADWAY, 10th FLOOR
NEW YORK, NY 10007
212-788-1400**

**CERTIFICATION / ANALYSIS
PURSUANT TO CHARTER SECTION 1043(d)**

RULE TITLE: Amendment of Health Code Article 13 (Reporting of Exposure to Certain Biological Agents)

REFERENCE NUMBER: DOHMH-62

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

- (i) Is understandable and written in plain language for the discrete regulated community or communities;
- (ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and
- (iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ [Stephen Narloch]
Mayor's Office of Operations

[3/7/16]
Date

**NEW YORK CITY LAW DEPARTMENT
DIVISION OF LEGAL COUNSEL
100 CHURCH STREET
NEW YORK, NY 10007
212-356-4028**

**CERTIFICATION PURSUANT TO
CHARTER §1043(d)**

RULE TITLE: Amendment of Health Code Article 13 (Reporting of Exposure to Certain Biological Agents)

REFERENCE NUMBER: 2015 RG 016

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

- (i) is drafted so as to accomplish the purpose of the authorizing provisions of law;
- (ii) is not in conflict with other applicable rules;
- (iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and
- (iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN
Acting Corporation Counsel

Date: March 7, 2016