



Building a Healthy Boston

BIOLOGICAL LABORATORY REGULATIONS FREQUENTLY ASKED QUESTIONS

11/25/2019

Purpose

This document supplements the text of the Biological Laboratory Regulations and Guidelines. It offers answers to some of the most commonly asked questions raised by the regulated community. References to specific sections of the Regulation and Guidelines have been included, as appropriate.

This document has three sections:

- a) General questions concerning all laboratory or permit types;
- b) Questions specific to BSL-2 labs seeking a recombinant DNA permit; and
- c) Questions specific to BSL3 and BSL4 labs seeking a Biological Laboratory Permit.

A) General Questions

1. What are the permit fees under the revised regulations?

The BPHC has modified the basis on which laboratory permit application fees are calculated, updated the fees, and introduced annual permit application fees for Recombinant DNA laboratories. Permit application fees are based on the size of the Regulated Laboratory Space, which is defined as the total floor area (in square feet) of the permitted biological laboratory at a single biosafety level, including animal rooms, waste storage rooms and other rooms directly serving the laboratory. The permit fees (for both new and annual renewal applications) are:

| Biological Laboratory Type | Size of Regulated Laboratory Space | Permit Fees (Annual) |
|---------------------------------|------------------------------------|----------------------|
| BSL-2/ABSL-2 using rDNA | 1-5,000 square feet | \$500 |
| | 5,001 to 10,000 square feet | \$1,000 |
| | 10,001 or more square feet | \$1,500 |
| BSL-3/ABSL-3 (Non-Select Agent) | 1 to 5,000 square feet | \$3,000 |
| | 5,001 to 10,000 square feet | \$7,000 |
| | 10,001 or more square feet | \$10,000 |
| BSL-3/ABSL-3 (Select Agent) | Any size | \$12,000 |
| BSL-4/ABSL-4 | Any size | \$60,000 |

2. Where can an institution find electronic copies of the Regulation, Guidelines, application forms, and incident reporting form?

All documents can be found on the BPHC website at the following links:

- Regulations and Guidelines:
<http://www.bphc.org/whatwedo/healthy-homes-environment/biological-safety/Pages/Regulatory-Links.aspx>
- Permit Application Forms:
<http://www.bphc.org/whatwedo/healthy-homes-environment/biological-safety/Pages/Inspection-Forms.aspx>
- Laboratory Incident Reporting Form:
<http://www.bphc.org/whatwedo/healthy-homes-environment/biological-safety/Pages/Inspection-Forms.aspx>

3. Must a large university with multiple academic schools/departments across multiple campuses, or an umbrella organization comprising several member or affiliate institutions within the City of Boston, apply for a single permit covering all the schools/departments or member/affiliate institutions? OR is each school/department or member/affiliate institution required to apply for a separate permit?

Each institution with a separate **Employer Identification Number (EIN)** issued by the Internal Revenue Service (IRS), will be required to apply for a separate permit. This provides the clearest way to identify separate organizational/functional entities that may be part of a cooperative network, report to a parent company, or are associated at a higher organizational level.

Example 1:

Entity A is a large academic/research institution with several schools located in two campuses in Boston. The schools operate as separate units under the corporation's decentralized system. The corporation has a single EIN, which is used by all the schools. The institution is required to apply for a single rDNA permit covering all the schools where rDNA research is done.

Example 2:

Entity B is a major hospital operating within a large health care system comprising several member or affiliate institutions located in Boston that also perform biological research work. The healthcare organization has its own EIN. It facilitates the regulatory compliance of the research done by the member institutions. Each member or affiliate institution has its own EIN. Each member or affiliate institution is required to apply for a separate

biological laboratory permit covering all its buildings in Boston where research is done.

Please note that clinical/medical diagnostic laboratories, and laboratories in educational institutions used exclusively for instruction but not for research experiments are specifically exempted from the permit requirement.

This is a benefit to each institution because its permit is not linked to that of any other institution in an umbrella organization/association. Any research lab found to be in violation of the Regulation faces the possibility of suspension of its permit. Separate permits prevent the chance of a problem with one institution in an affiliate network interrupting the work of the research labs at other institutions in the network.

4. If an institution has research laboratories at different biosafety levels (e.g. BSL-2 labs using rDNA and BSL-3/ABSL-3 labs), which permit(s) must it apply for?

An entity must apply for a permit for each applicable laboratory type. Using the example above, the entity would apply for a single rDNA Permit and a BSL-3/ABSL-3 Permit.

5. Does an institution with multiple buildings spread across a large campus or multiple campuses within the City of Boston need to list all the physical locations, including the buildings and room numbers, where rDNA materials or biological agents are used or stored when submitting a new or renewal application?

The institution is required to include a list of the street addresses (and building names used to identify specific buildings located on the same street address) of all the institution's properties in Boston containing Regulated Laboratory Spaces. A list of specific room numbers is not required. The BPHC may ask for more details or information if needed during the permit application review process.

B) BSL-2 Labs Requiring Recombinant DNA Permit

1. Is an institution with a current Recombinant DNA permit covering its BSL-2 lab required to apply for a New BSL-2/ABSL-2 (Recombinant DNA) Permit or a Renewal Permit?

Each institution with a current BPHC rDNA (BSL-2) Permit must apply for a **Renewal BSL-2/ABSL-2 (Recombinant DNA) Permit** by January 31, 2020.

The Renewal and New application both use the same application form which is available on the BPHC Biosafety Program website at:

<http://www.bphc.org/whatwedo/healthy-homes-environment/biological-safety/Pages/Inspection-Forms.aspx>

2. Is an institution with an active rDNA (BSL-2) Permit required to submit all the permit application documents listed in Section 4.1 of the Guidelines (New BSL-2/ABSL-2 Permit)?

As specified in Section 5.1(c) of the Guidelines, as part of the renewal permit application, each institution with a current rDNA (BSL-2) Permit is required to submit a list of the documents specified in Section 4.1(f) through 4.1(l) of the Guidelines. The list should include the document title, an indication if any changes have been made to the document since it was last submitted to BPHC, and a brief description of any such changes. The listed documents should be those that are currently used in the BSL-2/ABSL-2 (rDNA) labs in the institution.

Full documents should only be submitted with a renewal permit application if the document is new; if the applicant determines that the changes made since last submission to BPHC are so extensive such that it's easier to submit the entire document instead of describing the changes; or if the BPHC specifically requests a copy of the document during the permit application review.

If you have any questions about what should be submitted, please contact the BPHC Biosafety Office at 617-534 2683 or biosafety@bphc.org.

3. Is an institution with a current permit required to submit a list of all the current research protocols using rDNA to BPHC when applying for a Renewal BSL-2/ABSL-2 (Recombinant DNA) Permit?

No. An institution with a current rDNA Permit is **not** required to submit a list of all the current research protocols using rDNA when submitting a renewal application.

4. How should institutions report recombinant DNA exposures, such as lentivirus exposure?

The institution should call the BPHC Environmental Health Office at (617) 534-5965 during regular business hours or send an email

(biosafety@bphc.org) within 24 hours to report any accidental release, spills, or accidents in BSL-2 labs that cause an overt exposure to rDNA materials.

If the institution determines that the incident should be reported to the NIH OSP, a copy of the NIH Incident Report should be sent to BPHC Environmental Health Office (biosafety@bphc.org) within 30 days.

5. Is the institution required to report all BSL-2 lab workers who are absent from the workplace for more than two days?

Only if the employee's absence is caused or suspected of being caused by illness due to exposure to specific biological agents used or stored in the laboratory. The Guidelines specify in Section 8.1 that the institution is required to report any illness among persons caused or potentially caused by recombinant DNA material, a high-risk agent or attenuated strain of a high-risk agent present in a laboratory, and any absence of two or more consecutive workdays due to illness suspected of being related to exposure to a high-risk agent used or stored in the laboratory to BPHC.

The term "*High-Risk Agent*" is defined in the BPHC Biological Laboratory Regulations and a list of such High-Risk Agents that require reporting to BPHC is available on the BPHC's website at:

https://www.bphc.org/diseasereporting/Documents/Reporting%20Forms/Biologic_Research_Laboratory_Reporting_Form_3-13.pdf

If the illness is not caused or suspected of being caused by exposure to the above biohazards, it does **not** need to be reported to the BPHC.

C) BSL-3 and BSL-4 Labs

What is the process and timeline for review of new BSL3 research protocols and major amendments?

The institution must send copies of new BSL-3/ABSL-3 research protocols and major research protocol amendments approved by the institution's IBC, and copies of IBC approval letters to BPHC for review and approval. The BPHC will review the documents within 30 days. Minor protocol amendments (addition/removal of personnel, funding sources, change in room numbers within permitted lab space, etc.) don't require BPHC approval.