



# SIERRA CLUB

## LOMA PRIETA CHAPTER

SAN MATEO, SANTA CLARA & SAN BENITO COUNTIES

March 30, 2022

Honorable Mayor and Members of the City Council  
Chair and Members of the Planning Commission

**Subject: Planning Review and Entitlements of Biotech Developments**

Dear Members of the City Council and Planning Commission:

The Sustainable Land Use Committee of the Loma Prieta Chapter of the Sierra Club (SLU) advocates on land use issues in San Mateo and Santa Clara Counties. In that role, we are interested in the overall planning of our cities for the physical and environmental health of our communities.

More bio-tech development is being proposed in cities in San Mateo and Santa Clara Counties and most of these new developments are in highly urbanized locations. In an urbanized setting, the biological materials being studied could become a regional health hazard if allowed to escape. Furthermore, siting of such facilities in shoreline areas, identified as flood zones, can create vulnerabilities for the Bay ecology as sea levels rise and 100 year flood events occur with increased frequency.

Therefore, cities must be transparent and rigorous in approving these facilities from an environmental and public health perspective. To aid in that endeavor, we've attached the Sierra Club, Loma Prieta Chapter's *Guidelines for Biosafety Levels in Biotech Laboratories*.

Please consider all the planning review suggestions listed in the *Guidelines* before approving any new Bio-Tech developments in your city. Most EIR studies include air and water pollution and chemical hazards, but seldom include bio-hazards; yet bio-hazards can be far more dangerous than most other environmental concerns.

Please establish clear and effective new planning code requirements for Biotechnology developments, including monitoring, emergency and evacuation procedures, before approving any further projects. Thank you for your consideration.

Respectfully Yours,

Gita Dev, FAIA, Co-Chair  
Sustainable Land Use Committee  
Sierra Club Loma Prieta Chapter

Jennifer Chang Hetterly  
Bay Alive Campaign Lead  
Sierra Club Loma Prieta Chapter

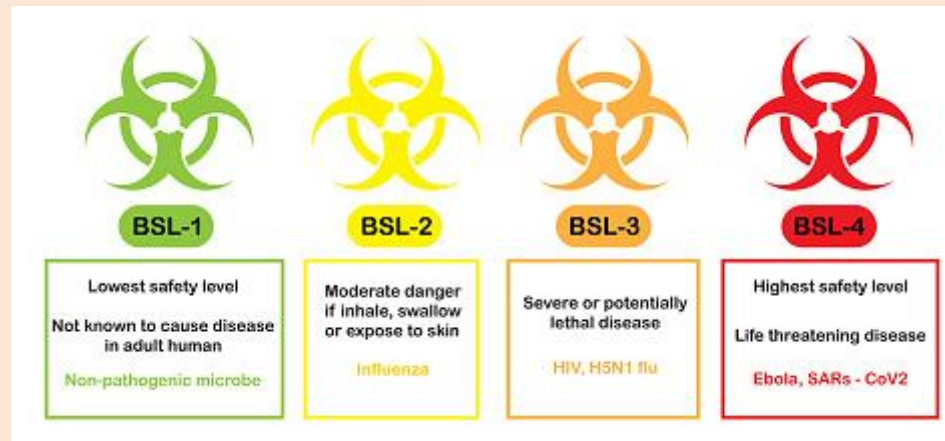
Cc: James Eggers, Executive Director, Sierra Club Loma Prieta Chapter  
Gladwyn d'Souza, Conservation Chair, Sierra Club Loma Prieta Chapter



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## Guidelines for Biosafety Levels in Biotech Laboratories



This is a brief overview of biosafety levels for research laboratories, drawing from Lab Manager ([www.labmanager.com](http://www.labmanager.com)) Updated Dec 27, 2021 ; November 15, 2021 and from the Centers for Disease Control and National Institutes of Health

In light of numerous proposed biotech developments in highly urbanized locations, this document provides a starting point for identifying issues in facilities using biological materials. Proper facility location and design for research or clinical labs, permitting, and operations are essential to ensuring that people working in the facility and the environment outside the facility are protected.

**As a matter of public health, cities must be rigorous in reviewing and approving these facilities.**

A specialized laboratory that deals with infectious agents is the biosafety lab. Biosafety labs may be devoted to research or to production activities and involve working with infectious materials or laboratory animals. It is essential to pay attention to the proper design of facilities, to proper protocols in using the facilities and procedures in the event of emergencies and disasters. Biological safety levels (BSL) are ranked from one to four, based on the agents or organisms used in the labs. Each higher level builds on the previous level, adding constraints and barriers. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) are the main sources for biological safety information for infectious agents. The publication *Biosafety in Microbiological and Biomedical Laboratories* <https://www.cdc.gov/labs/BMBL.html> is a principal reference.

The four biosafety levels were developed to protect against a world of select agents, including bacteria, fungi, parasites, prions, rickettsial agents and viruses (the largest group). When the work involves vertebrate animals, additional precautions and safety requirements are necessary. Studying the most infectious agents also means extensive security measures must be in place because of their virulence and because of their potential to escape the lab and infect the surrounding population, or for use in bioterrorism.

**Issues for City Planning Departments, County and City Departments of Public Health, City Planning Commissioners, and City Council Members to address when reviewing planning applications for developments including BIOTECH laboratories.**

Incidents involving biological, chemical, physical, and radiological hazards can have a significant impact on the safety and health of workers in laboratory settings. In addition, consideration needs to be given to risks to the community and the environment in the event of accidents, disasters and building failure. **This is particularly important if proposed developments are in proximity to vulnerable populations and delicate Bay ecosystems, and where risk of disruption from sea level and groundwater rise is high.**

- Determine the Biological Safety Levels (BSL) for the proposed project - Level 1, 2, 3, or 4. Decide which of these Levels are acceptable or not acceptable to the city from a public safety perspective. While Level 1 labs are generally considered safe, Level 2 labs are not advisable where there is the potential for structural failure. San Francisco Airport and all area airports do not permit Levels 2, 3 and 4 labs within some Land Use Safety Compatibility Zones. In addition, structural failure for biosafety lab buildings on soils subject to liquefaction in seismic events, such as bay fill, should be carefully considered as it could pose a community and environmental safety risk.
- Consider risks from flooding and infrastructure safety, including surface flooding and subsurface impacts from sea level and groundwater rise, for biosafety labs except Level 1.
- Consider prohibiting Level 3 and Level 4 labs, entirely, in urban and shoreline areas.
- Require the applicant to submit in writing the BSL for the proposed project with a provision that changing to a higher level BSL will not be allowed without prior review and approval by the city and may not be allowed at all if so determined by the city.
- In the case of a speculative development where the final tenants or buyers may not be known during the city entitlements process, include the allowed BSL in the entitlements and in the EIR. After entitlement, require the developer to submit, in writing, the BSL for each company that is being considered for rental or purchase of space in the development, as they occur, before the lease or purchase is finalized, to ensure compliance.
- Any change to the BSL level will need review at City Council level and may not be allowed. In addition, re-evaluation under CEQA may be required.
- Require the applicant to identify the range of diseases to be studied and the agents to be used in the proposed facility.
- Require the applicant to define emergency protocols and safety design features for the building(s) and surrounding area, including Bay wetlands.
- Require the applicant to define safety redundancy measures for HVAC and air exhaust systems, waste disposal and storm water management systems, water quality safety, etc. in the building(s) design and long-term use
- Require the applicant to identify any animals to be used in the research and how they will be housed, secured, and protected.
- Require rigorous environmental assessments for any potential air or water pollution, or waste disposal materials generated by the facility, especially airborne particles or bio-hazardous materials.
- Include a biological safety analysis and health impact report on potential short and long-term safety impacts on the city, the bay, and the regional environment. **This should be a key component of the Environmental Impact Review process.**
- Require a monitoring and verification program to ensure that the facility is complying with the city requirements and the proponent's commitments to the city and all related regulatory agencies (e.g. fire dept, Cal-OSHA, CDC, USDA, etc.) including inspections and violations reports.

**Reference:**

CDC and NIH—Biosafety in Microbiological and Biomedical Laboratories—6<sup>th</sup> Edition

<https://www.selectagents.gov/>

<p><b>Level 1</b></p> <p>Biosafety level one, the lowest level, applies to work with agents that do not consistently cause disease in healthy adults</p> <p>Non-pathogenic microbe</p>	<p>Biosafety level one, the lowest level, applies to work with agents that usually pose a minimal potential threat to laboratory workers and the environment and do not consistently cause disease in healthy adults. Research with these agents is generally performed on standard open laboratory benches without the use of special containment equipment. BSL 1 labs are not usually isolated from the general building. Lab personnel are trained and supervised on specific procedures by trained scientists.</p> <p>Standard microbiology practices, e.g. mechanical pipetting and safe sharps handling, are usually enough to protect laboratory workers and other employees in the building. Routine decontamination of work surfaces occurs, and potentially infectious materials are decontaminated prior to disposal, generally by autoclaving. Standard microbiological practices also include hand washing and a prohibition on eating or drinking in the lab. Lab workers wear normal personal protective equipment. Biohazard signs are posted and access to the lab is limited whenever infectious agents are present.</p>
<p><b>Level 2</b></p> <p>Biosafety level two covers work with agents associated with human disease, i.e., pathogenic or infectious organisms posing a moderate hazard.</p> <p>Influenza, salmonella,</p>	<p>Biosafety level two covers work with agents associated with human disease, i.e., pathogenic or infectious organisms posing a moderate hazard. Examples are the equine encephalitis viruses and HIV. Care is used to prevent percutaneous injury (needlesticks and cuts), ingestion and mucous membrane exposures in addition to the standard microbiological practices of BSL 1. Caution is used when handling and disposing of contaminated sharps. The laboratory's written biosafety manual details any needed immunizations (e.g., hepatitis B vaccine or TB skin testing). Access to the lab is more controlled than for BSL 1 facilities. Immunocompromised persons with increased risk for infection may be denied admittance at the discretion of the laboratory director.</p> <p>BSL 2 labs must also provide the next level of barriers, i.e., specialty safety equipment and facilities. Work with infectious agents involves a Class II biosafety cabinet, an autoclave, and an eyewash station. Self-closing lockable doors and biohazard warning signs are required at access points</p>
<p><b>Level 3</b></p> <p>These are indigenous or exotic agents that may cause serious or lethal disease via aerosol transmission.</p> <p>HIV, HSN1 flu, SARS-CoV2 plague</p>	<p>Yellow fever, St. Louis encephalitis and West Nile virus are examples of agents requiring biosafety level 3 practices and controls. Work with these agents must be registered with all appropriate government agencies. These are indigenous or exotic agents that may cause serious or lethal disease via aerosol transmission. Beyond the BSL 2 practices and equipment, work in BSL 3 labs involves tighter access control and decontamination of all wastes in the facility.</p> <p>More protective primary barriers are used in BSL 3 laboratories, including solid-front wraparound gowns, scrub suits or coveralls made of materials such as Tyvek® and respirators as necessary. Facility design incorporates self-closing double-door access separated from general building corridors. The ventilation must provide ducted, directional airflow by drawing air into the lab from clean areas and with no recirculation</p>
<p><b>Level 4</b></p> <p>Agents requiring BSL 4 facilities and practices are extremely dangerous and pose a high risk of life-threatening disease.</p> <p>Ebola, smallpox</p>	<p>Agents requiring BSL 4 facilities and practices are extremely dangerous and pose a high risk of life-threatening disease. Examples are the Ebola virus, the Lassa virus, and any agent with unknown risks of pathogenicity and transmission. BSL 4 facilities provide the maximum protection and containment, requiring complete clothing change before entry, a shower on exit, and decontamination of all materials prior to leaving the facility.</p> <p>The BSL 4 laboratory contains a Class III biological safety cabinet or equivalent in combination with a positive-pressure, air-supplied full-body suit. Usually, BSL 4 laboratories are in separate buildings or a totally isolated zone with dedicated supply and exhaust ventilation. Exhaust streams generally are filtered through high-efficiency particulate air (HEPA) filters.</p>