SIERRA CLUB
LOMA PRIETA CHAPTER

SAN MATEO, SANTA CLARA & SAN BENITO COUNTIES

November 11, 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 Sierra Club Loma Prieta Chapter's Sustainable Land Use Committee (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.

Bio-tech has brought us many great advantages in saving lives and food production. Bio-tech labs deal with a wide range of infectious agents from benign to lethal. Therefore, it comes with a certain level of risk. However, these risks are not well understood.

Cities need to manage the risks with a clear understanding of **differences between biosafety levels (BSL) 1- 4.** And they need the active assistance of the departments of public health, safety and emergency preparedness. Attached is the *Sierra Club's Guidelines for Biosafety Levels (BSL) in Biotech Laboratories* and a very **short video** of the differences between the basic types of bio-tech labs.

Historically, labs have been located in industrial zoning for public health reasons. Now, however, bio-tech development is being proposed in mixed use zones in cities in San Mateo and Santa Clara Counties. In an urbanized setting, some of the **biological infectious agents being studied, at BSL 2 and 3**, and animal research could create a health emergency in the event of human error, accidents or in disasters such as serious seismic events. Furthermore, siting of such facilities in shoreline areas, identified as flood zones and high liquefaction zones, can create potential vulnerabilities for the regional Bay ecology and human health should public infrastructure be compromised and emergency protocols fail.

East Coast cities, where bio-tech has had a long history, provide early guidance to facilitate development through their zoning and other early mechanisms, as bio-hazards can be potentially more serious than many other impacts.

We hope your city will study and establish clear and effective new planning code requirements for Biotechnology developments, including zoning, permiting, monitoring and emergency procedures, before approving further projects. Thank you for your consideration.

Respectfully Yours,

Gita Dev, FAIA, Co-Chair
Sustainable Land Use Committee

Jennifer Chang Hetterly
Bay Alive Campaign Lead

Cc: Planning Director and Housing Commission members
James Eggers, Executive Director, Sierra Club Loma Prieta Chapter
Gladwyn d'Souza, Conservation Chair, Sierra Club Loma Prieta Chapter

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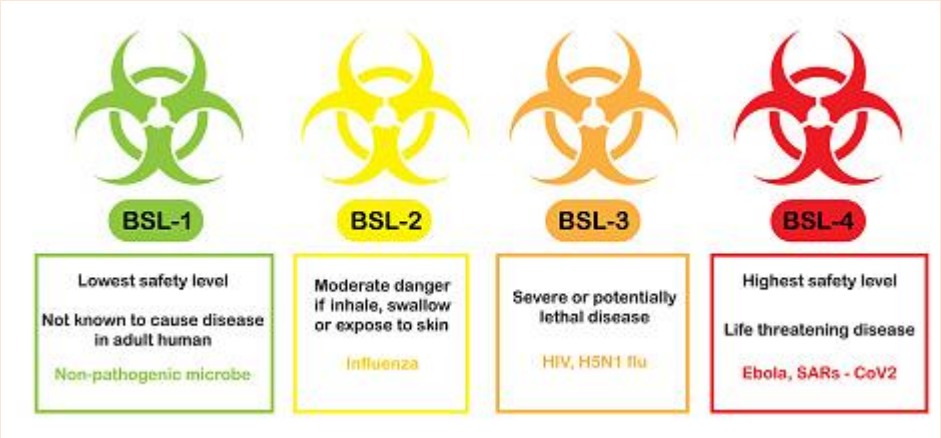
Guidelines for Biosafety Levels (BSL) in Biotech Laboratories



This is a brief overview of biosafety levels for research laboratories, drawing from Lab Manager (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 as well as the public and the environment outside the facility are protected.

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

A specialized biotech 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 these 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 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).

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, environment** or for use in bioterrorism. When the work involves vertebrate animals, additional precautions and safety requirements are necessary.

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.

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 fragile Bay ecosystems, and where risk of disruption from seismic disasters and sea level and groundwater rise is high.**

- Determine the Biological Safety Levels 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, or above, within some Land Use Safety Compatibility Zones. In addition, structural or infrastructure 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/or environmental safety risk.
- Consider prohibiting Level 3 and Level 4 labs, entirely, in urban and shoreline areas, because of public safety.
- Consider risks from flooding and public infrastructure safety, including flooding and subsurface impacts from sea level and groundwater rise, for biosafety labs above Level 1.
- 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 if animals will 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—6th Edition
https://www.selectagents.gov/

Level 1 Biosafety level one, the lowest level, applies to work with agents that do not consistently cause disease in healthy adults Non-pathogenic microbe	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. 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.
Level 2 Biosafety level two covers work with agents associated with human disease, i.e., pathogenic or infectious organisms posing a moderate hazard. Influenza, salmonella,	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. 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
Level 3 These are indigenous or exotic agents that may cause serious or lethal disease **via aerosol transmission.** HIV, HSN1 flu, SARS-CoV2 plague, anthrax	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. 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
Level 4 Agents requiring BSL 4 facilities and practices are extremely dangerous and pose a high risk of life-threatening disease. Ebola, smallpox	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. 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.