Final Environmental Impact Report
1125 O'Brien Drive Project
Appendices

Prepared by:
ICF

Prepared for:
City of Menlo Park

September 2023

FINAL
ENVIRONMENTAL IMPACT REPORT

1125 O'BRIEN DRIVE PROJECT

APPENDICES

PREPARED FOR:

City of Menlo Park
701 Laurel Street
Menlo Park, CA 94025

PREPARED BY:

ICF
201 Mission Street, Suite 1500
San Francisco, CA 94105

SEPTEMBER 2023

Appendix 1

Planning Commission Hearing Transcript

925-831-9029 emerickfinch@emerickfinch.com

CITY OF MENLO PARK

Planning Commission

In re:

Draft Environmental Impact Report (Draft EIR) Public Hearing/ Tarlton Properties, LLC/1105-1165 O'Brien Drive and 1 Casey Court (referred to as the 1125 O'Brien Drive project)

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ENVIRONMENTAL IMPACT REPORT
REPORTER'S TRANSCRIPT OF PROCEEDINGS
AGENDA ITEM F2
MONDAY, APRIL 10, 2023

Reported by AMBER ABREU-PEIXOTO
(Via ZOOM Videoconference)
Certified Shorthand Reporter No. 13546
State of California

ATTENDEES

The Planning Commission:

Cynthia Harris - Acting Chairperson
Andrew Barnes
Michele Tate
Henry Riggs

SUPPORT STAFF:

Matt Pruter, Associate Planner
Corinna Sandmeier, Principal Planner

PROJECT PRESENTERS:
David Hogan, Contract Planner
John Tarlton, Tarlton Properties

CONSULTANTS:
Elke MacGregor, DES Architects & Engineers
Victoria Chung, ICF

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BE IT REMEMBERED that, pursuant to Notice of the Meeting, and on April 10, 2023, via ZOOM Videoconference, before me, AMBER ABREU-PEIXOTO, CSR 13546, State of California, there commenced a Planning Commission meeting under the provisions of the City of Menlo Park.

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MEETING AGENDA

--o0o--

P R O C E E D I N G S

ACTING CHAIR HARRIS: We are now moving on in the Agenda in F2 and G1, which are associated, with a single Staff Report. And I'm going to read F2. It's rather long, so just bear with me.

It's a Draft Environmental Impact Report for Tarlton Properties at 1105 to 1165 O'Brien Drive and 1 Casey Court, which we're going to refer to as 1125 O'Brien Drive Project.

The public hearing is to receive comments on the Draft EIR to develop a five-story research and development building containing approximately 131,000 square feet of gross floor area in the Life Sciences, Bonus zoning district. This includes 129,000 of R&D, and 2,659 square feet of commercial cafe uses.

The project site consists of four parcels, containing three one-story buildings with approximately 29,860 square feet and will be referred to as 1125 O'Brien Drive.

The proposed project would include 229 parking spaces in surface parking lots located behind the building and adjacent to the building along O'Brien Drive. The proposed project includes requests for a use permit, architectural control, below market rate housing in-lieu

fee, and environmental review.

The proposal includes a request for an increase in height and FAR under the bonus level development allowance in exchange for community amenities. The applicant is proposing payment of a community amenities in-lieu fee. The project includes a hazardous materials use permit request to allow a diesel generator to operate the facilities in the event of a power outage or emergency.

The proposed project includes requests to modify the surface parking along street frontage requirements along Casey Court and to transfer development rights in height from the applicant-controlled parcel at 1140 O'Brien Drive to comply with the Zoning Ordinance average height requirement.

The proposed project is requesting an exception from the City's reach code to allow for the use of natural gas for space conditioning and laboratory spaces.

The proposed project also includes a request to remove 11 heritage trees.

The focused Draft EIR was prepared to address potential physical environmental effects of the proposed project in the following areas: Transportation, population and housing, air quality, greenhouse gas emissions, noise -- and that's with operation, traffic

noise, construction noise, and vibration, cultural and tribal resources, and biological resources.

The Draft EIR identifies significant and unavoidable environmental impacts from noise and greenhouse gases. And the City is requesting comments on the content of this Draft EIR. Written comments on the Draft EIR may be submitted to the Community Development Department at 701 Laurel Street no later than 5:00 p.m., on May 8th, of 2023.

So as we discussed, the EIR staff, would you like to advise the -- how you would like to proceed; if there is a staff presentation and EIR consultant presentation, applicant presentation?

MR. HOGAN: Vice Chairman, I guess I will begin. My name is Dave Hogan. I'm the contract planner on this project. We had envisioned, with the Commission's permission, to have three presentations tonight. The first, an introduction by staff, followed up by a presentation by the project applicant, and then ending with the presentation by the City's EIR consultant to help frame in the comments on the EIR.

So if that's acceptable, then we will -- I will begin with my presentation.

ACTING CHAIR HARRIS: Thank you, Mr. Hogan. That sounds like a plan.

MR. HOGAN: Fantastic.

This is item F2, which is the public hearing on the Draft Environmental Impact Report.

Next, please, because I don't have -- there we go.

So our recommended format for the evening is starting off with a Draft EIR. Then again, as I said, my -- you'll have my presentation, then the presentation by the applicant, presentation by the EIR consultant. At that point, we're recommending that you open up the public hearing to receive public comments on the Draft EIR, comments on the EIR, on environmental issues. Even if they're not in writing -- if they are presented verbally tonight, they'll still be evaluated by the City and the EIR consultant and incorporated in a Response to Comments in the Final EIR.

After public comments, then we would recommend that the Commission provide comments on the Draft EIR. And when all the comments on the EIR, not necessarily the design of the project, then staff would recommend that you close the draft -- the public hearing, which would be item F2, and then go to item G1. Again, there will be a very brief introduction by staff.

Commissioner questions on the project, on the staff report, and those will be answered by either staff

or the applicant, depending upon the nature of the question.

At that point, we would recommend that the public comments on the proposed project be made available. And then after the public has commented, then we'd like to see the Commission's comments on the proposed project.

Next, please. Thank you.

Okay. This just gives a general location for the project. You can -- you see the Facebook -- Commissioners, can you see my mouse on the screen?

ACTING CHAIR HARRIS: Is it moving? Move it a little.

MR. HOGAN: Yeah. Okay. Maybe not. Okay. Never mind.

You can see the project is -- consists of four lots and largely, right in the industrial area of the city. Yeah. There it is. And then you can see the residential areas surrounding it and its location. You see the Facebook campus at the top.

Next slide, please. Thank you.

This is the zoning map. Based upon the ConnectMenlo process the City went through, a lot of this area was redesignated to life sciences. The properties north of O'Brien Drive all have the life science bonus. The life science areas adjacent to East Palo Alto and the

residential neighborhoods there do not have the balance, do not have the bonus potential. Okay.

Next -- next slide, please. Thank you.

So there are five future actions on this project. First is the environmental review. That's what we're discussing.

There's also a use permit request for the generator and some of the parking issues. The actual use is permitted. So the use is permitted under the Zoning Code. The use permit is for other design elements.

Then there's architectural review, which is definitely something that we would like to hear back from the Commission on tonight, on the design of the building and design of the site. One of the issues is going to be a lot merger, and we will be -- in your Staff Report, I believe it is attachment B, shows the three lots being merged into one, which is being called Parcel 1 of the project.

Parcel 2 is the existing parcel, which is going to be the accessory parking lot. And, of course, there is heritage tree removal permits.

As the applicant went through this process, two of the 13 heritage trees -- the project then was modified to preserve those on-site.

Next, please.

Here we have a close-up of the site of the applicant. We'll go into much more detail. See Parcel 1 with the building, and Parcel 2, which is just the parking lot above that. The two parking lots do not connect internally, and that was something that staff would potentially like the Commission's feedback on.

Next, please.

So this is a reminder to a lot of the people monitoring the meeting. There's two elements tonight. And we've talked about it previously. The first is getting comments on the Draft Environmental Impact Report. Then there's a study session, getting design comments on the project. The Commission will not be taking any formal actions tonight on the project or the Draft EIR. The comment period ends on Monday, May 8th, at 5:00 p.m. So all comments received before that will be evaluated.

And in the final event, the Planning Commission will be the final decisionmaking body that will certify the EIR and consider the land -- various land use entitlements that the applicant has submitted for.

Next, please. Thank you.

I am just about done with my brief presentation. Next we will have the project applicant, and then followed by the EIR consultant. And at that point we will -- we are recommending that you open up the public hearing, get

comments from the public, your comments, and then we will proceed with the study session.

And next, please.

That concludes my presentation. And I'd ask that the applicant's presentation be loaded up and give them the opportunity to share their project with the Commission.

Thank you.

ACTING CHAIR HARRIS: Thank you.

To the applicant, please.

(Audio disruption.)

JOHN TARLTON: ... EIR consultants for all their hard work, and each of you for the service you provide to the City in reviewing applications like ours and participating in countless hours of public hearings.

In an effort to be efficient, my comments will be tailored to both the EIR comment agenda item and the study session. The proposed project, which has received positive feedback from this body several times over the last four-and-a-half years, has been updated to incorporate comments we received during our last public hearing, in addition to feedback from staff.

As you all know, because you've -- you've heard me up here a couple of times, the Menlo Park Life Sciences District has been quitely churning out world-changing life

science innovations for 40 years, from the original nicotine patch to the first commercially-available pan cancer biopsy, not to mention the first commercially-available COVID-19 test in the U.S. Menlo Park labs has helped future dozens and dozens of innovations that have simultaneously lowered the cost of health care and improved patient outcomes.

Menlo Park labs has also been home to several sustainability leaders. You may be pleased to know that Impossible Foods, formerly Meat 2.0, was born in a building right across the street from this project, and our latest addition to the park, Windfall Bio, who is enabling climate-positive agriculture. At the same time, Menlo Park labs has been a leader in creating jobs across a broad socioeconomic and education spectrum and significant sales tax revenue for the City.

Finally, we have led in our own sustainable practices, often adopting and instituting sustainable practices long before they are required. And that sometimes set the new standards for others.

Since our last presentation, we have modified the project to address concerns previously raised by the Planning Commission, as well as by staff. You will see these changes in more detail later in the presentation.

I'd like to call your attention to two specific

areas: One is the potential heat island effect of surface parking areas. As you will see, we will be planting a large number of trees on this project. Many of these will help shade the parking areas. In addition, we will be utilizing solar-reflective materials in the parking areas to dramatically reduce residual heat island effect.

The second is connectivity. With the help of staff, we've been able to create a new pedestrian connection that will provide future access to the Willow Village site for both Menlo Park and East Palo Alto residents and visitors. There's a visual of this later in the presentation.

I'm available for questions, but with that, I will turn over the presentation to Elke MacGregor, an incredibly talented architect, who has successfully led countless life science projects for our team.

ELKE MACGREGOR: Good evening, Commissioners. I'm Elke MacGregor, with DES. And this is our 18th building that we've built with Tarlton Properties in Menlo Park. Kind of cool.

The focus on those buildings in the last 15 years has been life science. And this building is located in the center of the Life Science District.

Should I be looking at -- thank you.

Next.

So the circle there indicates where this building is in the center of the Life Science campus. And it is a block from residential. It's adjacent to the Hetch Hetchy, which runs through the center of the park and through the center of the Life Science District. It also borders Willow Village. So, yeah. Thanks.

It -- in this sketch here, you can see the whole, sort of, tree-planted street that's O'Brien Drive, that connects Willow to University. This drive was identified in ConnectMenlo as an area where they wanted to have a Class II bicycle connection. So in our building, as in most of the buildings in the park, we have bicycle parking at the interior and exterior, as well as shower facilities.

There's also a shuttle service that extends throughout the whole Menlo Park labs to provide connection to the adjacent public transit areas.

We have multiple traffic reduction measures that are included in this project. This goes into a list of some of those.

The shower/changing facilities on-site here are also complemented at the fitness center, which is two blocks down the road on O'Brien Drive.

The traffic reduction that we've been able to do on this site -- or what we're planning on this site is

bolstered by the efficiency that we've achieved on other projects. So our estimated efficiency, we usually double that on our projects. And we've reduced traffic nearly twice what the code requirements are.

Next slide, please.

This is -- these are some of the buildings in the current Menlo Park lab site. There are multiple large and small tenants on campus here. One of those is Pacific Biosciences, in the bottom left corner. And the top right and bottom right are images of the cafe that's on campus. It serves the area for all of the local people. So this is for the neighborhood, as well as the people that are in the buildings on campus. There's also a fitness center on-site.

The next slide, please.

There currently are four buildings, plus a mechanical shed on-site. These are all concrete-tilt buildings that will be replaced with a new building.

John mentioned that we had a garage on-site previously in the last image. So we are now -- we purchased the property adjacent. So the three concrete tilt buildings, plus the one behind it, will now be a building plus a parking at grade, which I think was preferred by the Planning Commission, I think, for future flexibility in the last time we were presenting this in

2018.

These are the images of those marvelous buildings. They probably were marvelous at one point. So this is just a quick image that shows you the two properties. The one on top, which is hatched, which will become parking; and the bottom one, which has the existing three concrete tilt buildings.

This slide shows you the connection that we're proposing. And we worked with Planning Commission. This wasn't a request from the Planning Commission. It was from the Planning Department, but it was definitely something we discussed at the last meeting, and it was the ability to provide a connection for the residents of Palo -- or Menlo Park through our property site, up to the Hetch Hetchy and future Willow Village connection.

So this provides connection from Kavanaugh Street and O'Brien Drive, between the two properties and up to the Hetch Hetchy area. This is provided by way of a meandering path. It shows it better on the next slide. What this slide indicates is, we are exceeding the public and the private open space requirements for the City.

This slide shows you that that pathway is tree covered. It provides lots of points of connection to adjacent buildings, in addition to having some open space seating that is also tree-shaded.

We kept as many healthy trees on the property as we could. Quite a few of them are high water or no longer in great shape. So the ones we did keep are what was possible for the site.

This building is going to be LEED Gold. We've been working with the mechanical, electrical, plumbing, structural teams, and our sustainability team, to provide quality daylighting views for the tenants, reduce the environmental footprint, and also incorporate sustainable materials.

The connecting pathway -- this shows you there's a cafe included on the main floor of the building in the bottom right-hand corner. That opens up to a plaza adjacent to the building and provides public open space, as well as the amenities pictured here to all of the local neighborhoods, as well as to the building tenants.

And the last slide is an image of some of the finishes. We have, of course, bird-safe glass on the building. The glazing on this building is scientifically specific tinted. It's low E. And the sod materials have been selected for longevity and beauty.

Next slide.

These are the last two images of the building. This is the overall facade. And the next slide shows you the entrance, if you're walking a little closer to the

building. You're looking at a view into the entry. To the right of the entrance is a conference room and a cafe facility that would be open to the public.

Thank you.

ACTING CHAIR HARRIS: Thank you. I'll move on to the EIR consultant.

VICTORIA CHUNG: Can we pull up our presentation? Thank you.

Good evening, Acting Chair Harris, Commissioners, and members of the public. My name is Victoria Chung, and I am the Project Manager for the 1125 O'Brien Drive project EIR.

Next slide.

We worked with the City of Menlo Park's Planning Department, along with Hexagon, who was the traffic consultant, and KMA, who did the housing needs' assessment on this -- on this EIR document.

Next slide.

So tonight I'll be going over the following presentation topics: The purpose of this hearing; project overview; the environmental review process; the overview of the Draft Environmental Impact Report, aka, EIR; the next steps in the CEQA process; and how to comment on the Draft EIR.

Next slide.

So the purpose of this public hearing is to summarize the proposed project and conclusions in the Draft EIR, and to provide an overview of the CEQA process and next steps; to receive public input on the analyses in the Draft EIR; and, finally, to review next steps in the CEQA process.

Next slide.

So the applicant and City staff have already gone over the project -- the proposed project, but basically, for our EIR, we sort of separated the bottom portion of the project as Parcel 1, and the top portion of the project as Parcel 2, just to make the more technical areas of analyses easier for us. And you'll see why, when we get to -- when we discuss the impacts that are going to occur in the -- for the project.

Next slide.

So this is generally for the general public, but the environmental review process and the purpose of CEQA, it provides decisionmakers with -- and the public with information about the significant environmental effects of the proposed project, and to also identify potential peaceful mitigation and alternatives that would reduce significant effects to the project.

And also, the environmental review process focuses on -- of the analyses focuses on the physical

impacts of the environment. And lastly, it is so that the agency decisionmakers are able to consider the EIR and other input in making the -- your decisions on the project.

Next slide.

So the environmental review process -- we're just going to focus on the black boxes for now. And then we'll discuss the gray boxes towards the end of this presentation.

So the Notice of Preparation and the initial study was done between July 30th, 2021, and August 31st, 2021. The scoping meeting occurred August 9th, 2021, and that was to receive comments on the scope of the EIR.

And then the Draft EIR is currently under public review. And it's a 45-day public review period, and it started March 31st, and ends on May 8th, 2023.

And then, lastly, we're here at the public hearing today to discuss the EIR.

So the initial study that was done in 2021, it scoped out several impact areas. And so this is why this EIR has -- is primarily concentrated on specific impact areas.

The project itself is within the ConnectMenlo study area, and tiers off the ConnectMenlo EIR. This is required by CEQA, for projects that have -- that may have

significant environmental impacts. It identifies potential physical, environmental impacts of the project.

This informs the public and public agency decisionmakers, prior to project approval or disapproval, and recommends ways to reduce significant effects, and also considers project alternatives that may lessen potential impacts.

Next slide.

So the issues that are studied in this focused EIR are air quality, biological resources, cultural and tribal resources, greenhouse gases, noise, population and housing, transportation, and alternatives.

So the impacts and mitigation measures that we found, that we concluded in this EIR, we had significant and unavoidable impacts. Those were related to greenhouse gas. And there's a little error. It wasn't during construction; it was during operation. And that's due to the Bay Area Air Quality Management District's new updated thresholds, which is why we had to do the all-electric feasibility study.

And then the other significant and unavoidable impacts were related to construction noise and vibration. And this was due to the City's noise thresholds in relation to ambient noise.

And vibration. Significant unavoidable impacts.

That was due to potential construction being close to commercial areas. And that was -- it's vibration annoyance, and not -- related to vibration annoyances.

The EIR also found that the less-than-significant with implementation of mitigation measures were related to transportation, air quality, greenhouse gas, noise, cultural and tribal cultural resources, and biological resources.

Next slide.

And then, lastly, these issue areas found that there would be less than significant impacts with implementation of mitigation measures in this initial study. So those were cultural resources, geology and soils, and hazards.

Next slide.

At -- in our EIR, we discussed three different project alternatives. The first alternative is required by CEQA, which is the no-project alternative, which would assume that the existing uses on site and site conditions wouldn't change. So all four buildings would stay the same. No development would happen. All buildings on O'Brien Drive and Casey Court would remain in their current state.

The next alternative is the base level alternative, and that involves new development consistent

with the base level of development allowed by the City's Zoning Code, which is up to 55 percent floor area ratio, on both Parcel 1 and Parcel 2. And this was selected based on its potential to reduce the transportation and greenhouse gas emission impacts.

And then, finally, the environmentally-superior alternative, which is the reduced space level alternative. That involves development consistent with the base level development allowed by the City's Zoning Code; again, up to 55 percent floor area ratio, but the development would only happen on Parcel 1. And Parcel 2 would remain the same.

And the existing site uses and conditions would be available for future redevelopment, but development would primarily happen on Parcel 1.

Next slide.

And so what are the next steps for the environmental review process? We would -- after public hearing and collecting the comments during the public comment period, we would prepare the Final EIR that addresses the Response to Comments received in the Draft EIR comment period.

And then it would be up to the decisionmakers to take action on whether to approve the proposed project and EIR.

And if you would like to comment via e-mail, you would e-mail David Hogan at DWHogan@MenloPark.gov, or via letter and sending in the letter to David Hogan, Contract Planner, Community Development Department, Planning Division, at 701 Laurel Street, Menlo Park, California 94025, or tonight you could raise your hand via Zoom, and you'll be notified to speak. And all comments must be received by May 8th, at 5:00 p.m.

And that concludes my presentation.

Thank you.

ACTING CHAIR HARRIS: Thank you, Ms. Chung.

Okay. With the presentations completed, I'd like to ask the Commission if there are any clarifying questions before we turn to public comment on the EIR.

Okay. Seeing none, I would like to open up public comment. And I just want to remind the public that these are comments for the EIR. We will have another option for public comment when we bring back the project to the study session. So please only raise your hand now if you have comments that relate to the Draft EIR.

All right. So, please. Let's -- how many -- do we have hands raised?

MR. PRUTER: Yes, we do. Thank you, Chair Harris. At the moment, I see three hands raised. Happy to give the comment period -- now we have four.

And as a reminder, anyone on Zoom, please press your hand icon, if you'd like to speak, or press star nine on the phone, if you're calling in. Or if you're in person, please come by with a comment card to yours truly, and I can assist with in-person commenting as well.

Happy to begin, if you'd like.

ACTING CHAIR HARRIS: Thank you. Let's begin.

MR. PRUTER: Thank you. Our first commenter is Gita Dev. I'll allow you to speak at this time. And you'll have three minutes in just one moment.

Okay. I'm going to allow you to un-mute yourself. You'll have three minutes. Sorry about that. Thank you.

GITA DEV: Am I un-muted? Hello?

MR. PRUTER: Yes, you are. We can hear you. Thank you.

GITA DEV: Okay. Great. Thank you.

PC-1

Good evening. This is Gita Dev, with the Sierra Club, Loma Prieta Chapter. I wanted to bring up two comments regarding the EIR. One is, I just wanted to mention that in -- I believe in other cities, the biotech labs are able to have their HVAC systems not using natural gas. Most cities do allow natural gas to be used in the lab spaces because of the Bunsen Burners for experiments. But the actual heating and ventilating systems, I do not

PC-1 Cont.

believe they allow them to use natural gas. So I have not read the justification report, but I just wanted to mention that.

PC-2

The other item was that there is not a water budget that's being mentioned in the EIR. And it mentioned there is a process for looking at a water budget after one year, but it does not say at this point any presumption of what the water budget might be. And I just wanted to know what that expectation is. I believe it should be spelled out.

One other item which the EIR doesn't seem to address very well is -- maybe it doesn't have a good category for it. What's the biosafety level? Are we assuming these will be biosafety labs, Level 1 and Level 2?

PC-3

But if there is anticipation to have biosafety Level 3, then that brings up a lot of environmental concerns because these are transmitted -- aerosol transmission have extremely stringent HVAC requirements and containment requirements. And those are -- there are a lot of environmental impacts from potential -- potential release of these agents. So the EIR is lacking in that area. I just wanted to bring that up.

PC-4

The final item is noise. There seems to be a good amount of study done on the noise. However, they

PC-4 Cont.

make it very clear that they have no idea what actual equipment might be there or that -- when they're all on simultaneously, it could be extremely noisy. So this is an issue that has been brought up many times before with you guys to labs, and they are very robust HVAC systems.

Thank you very much.

MR. PRUTER: All right. Thank you for your comment.

Our next commenter is Lynne Bramlett. I'm going to allow you to un-mute yourself now. You'll have three minutes as well. Thank you.

LYNNE BRAMLETT: Good evening, Commissioners. I'm Lynne Bramlett, resident of District III, Mills Court. I'm also the leader of MPC Ready, which is a neighborhood-level disaster preparedness organization.

Tonight I'm speaking for myself. However, as the leader of MPC Ready, I've become quite informed about our areas' general preparedness or not for a disaster. And what I see in District I -- I realize this is a comment on the EIR, is a general piecemeal approach to development that I think new information warrants a review.

It also is starting very late at night, and the public is commenting after 9:30. And to my knowledge, the City has not conducted trainings, especially in District I, on how to comment effectively on EIRs.

This -- one of the prior speakers mentioned ConnectMenlo. I continue to hear tiering off ConnectMenlo EIR. However, the ConnectMenlo EIR is -- the program level EIR dismissed the threat of the Hayward Fault eruption, which is a very real hazard, with potentially significant impacts to Menlo Park. And I can say, in my role with MPC Ready, though I'm speaking for myself, the City of Menlo Park, the County of San Mateo, and the Menlo Park Fire Protection District are all completely un-prepared for bio-hazards or a bio-hazard-release incident, and also un-prepared for the eruption of the Hayward Fault.

PC-5

So it seems to me that these EIR meetings don't take into account kind of a new model that incorporates issues pertaining to general safety, especially safety of the residents living near these areas; East Palo Alto, Belle Haven and, you know, any problems could very certainly affect not just that area, but the rest of Menlo Park.

PC-6

So I agree with the speaker from the Sierra Club, the woman who spoke before me, with her concerns that she's raising; water, noise. I think a lot of concerns are kind of -- there is an adequate fact base assurances that the water will be there, et cetera.

PC-7

So thank you, Commissioners, for your time

tonight. I think the industry itself should be looked at more from a public safety point of view.

Thank you.

MR. PRUTER: Thank you very much.

Our next commenter is Naomi Goodman. I'm going to let you un-mute yourself at this time as well. And you'll have three minutes to speak.

Thank you.

NAOMI GOODMAN: Can you hear me?

MR. PRUTER: Yes, we can.

NAOMI GOODMAN: Okay. Good. Thank you.

My name is Naomi Goodman. I'm speaking for myself, as a resident of Menlo Park District II.

PC-8

Similar to the previous speakers, I have concerns regarding the lack of information in the EIR on the types of R&D that would be allowed in the proposed Life Sciences Building. It's located within 500 feet of a residential area and an elementary school in a high-hazard liquefaction zone.

PC-9

Biotech research can run the gamut from innocuous to deadly, if a biological agent escapes from a lab. Such escapes do happen. I refer you to the U.S. Right to Know website for examples. The residents of Menlo Park and East Palo Alto deserve transparency on the risks to which they could be unknowingly exposed.

Neither the ConnectMenlo or the Draft EIR addresses allowable biosafety levels. Tenants could engage in research, requiring biosafety Level III containment. BSL III labs handle high-risk pathogens that are difficult to control, as they're airborne and very contagious when released. Containment depends on mechanical systems that can fail through human error, mechanical failure, or disasters. These labs are appropriate where there's scientific safety oversight committees that ensure and understand these risks.

PC-9 Cont.

Menlo Park does not have such a committee in place, and no other government agency has any responsibility for the safety of private biotech labs. Menlo Park is not prepared at present to take the role of guardian of public safety for biotech labs.

PC-10

If the project is approved, the use permit should stipulate there will be no R&D requiring BSL III procedures, and a process should be set up by Menlo Park to verify those assurances.

Failure to consider potential impacts of future uses of the building is a major flaw in the EIR. I request that the Final EIR evaluate the potential for human health and ecological hazard from the spectrum of target organisms that may be used in the building.

PC-11

Thank you.

MR. PRUTER: Thank you very much.

Our next commenter is Jenny Michel. I'd like to add, this appears to be the last commenter with their hand raised at this time. So I'm going to let you be able to speak. And you'll have three minutes starting now.

Thank you.

JENNY MICHEL: Good evening, Chair, Vice Chair, Commissioners, Staff, neighbors, members of the public. My name is Jenny Michel, from the Coleman Place Neighborhood Blog, bringing you tales from the leverage labor cribs; long-time renting resident on Willow Road, mother of IEP student, recovering homeless teacher, and by trade, a commercial property manager.

PC-12

I support this applicant and the incredible inherent values you bring to our city. I'm excited about this development opportunity, both as a colleague in the industry, but also as a lights-on resident and parent.

PC-13

One thing I'd like to call out, to ask this body to require or enact some mechanism to ensure this applicant hires local labor. In the spirit of the EIR, reducing vehicle miles driven and investing in local families is a bonus win-win to all.

As a world-class employer, we would hope, as residents, that you believe in us and offer us the opportunity to work with you on future endeavors.

PC-13 Cont.

Stabilizing the local labor force is an understated urgent priority to minimize overall risk applicable to all real property assets, which always impacts the environmental scope of a project.

PC-14

To the public comments, reinforcing the structure to secure the residents away from some type of contamination, knowing that you're in a liquefaction zone, prone to water rise implications is a must. And although the area is zoned for the biolab pursuit, it does not take into consideration the risks of -- associated with such use.

PC-15

The applicant is encouraged to support moving away from gas components. Outside of that, I appreciate your due diligence and your proposing this forward-looking project.

All my best, Jenny.

MR. PRUTER: Thank you very much for your comment.

At this time I see no additional commenter hands raised, and no one from the council chambers is looking to provide a comment as well. We've waited for a little while. If you would like to wait a moment longer, Acting Chair Harris, or we could close the public comment period for this particular part of the item.

ACTING CHAIR HARRIS: I think that we've waited

long enough. We can close public comment and bring it back to the Commission for discussion and questions related to the EIR.

Who would like to start?

Commissioner Riggs?

COMMISSIONER RIGGS: Yes. Thank you.

Although public comment by three Zoom participants is not exactly a representative of an overall city-wide reaction, one cannot help but notice the recurring theme regarding biosafety. So I would like to ask, through the Chair, if I may, ask of staff, when the tenants apply to Tarlton Properties to do their tenant improvements, is their scope of work brought to us for tenant space review?

PC-16

MS. SANDMEIER: Through the Chair. So the normal procedure is for it to go to outside agencies, including county health and the fire district. And based on input, we can always update that process also.

And I think we have David Hogan here, too, to answer more specific questions about the project.

MR. HOGAN: At the -- Commissioners, at this point, according to the applicant, they don't have a specific tenant. So it's hard for staff to identify, you know, who is actually going to be in the building.

The Zoning Code does not provide specific

direction on how to address the different bio levels. Once the Commission receives this project, either the applicant will have a better idea of who their tenant will be and/or the Commission will be in a position then to consider the appropriate level or other requirements they might see that they think is appropriate, in terms of limiting or not limiting the bio level and the proposed building for future tenants.

COMMISSIONER RIGGS: All right. If I may summarize, then. This is the meeting. This is the hearing. This is the opportunity to talk about bio-hazard levels.

PC-17

Is that correct, Mr. Hogan?

MR. HOGAN: From the perspective of the EIR, I would say yes. If you think that the EIR should address it, then I think this is a good time. Otherwise, I would suggest that maybe doing that as part of the study session might be a little bit more focused on the issue because that will facilitate staff and the applicant, in terms of taking the steps necessary to begin to address the Commission's concerns.

COMMISSIONER RIGGS: Agreed. Thank you very much.

MS. SANDMEIER: And through the Chair, I did want to clarify, any future tenant improvements would not go to

the Planning Commission. So those would go through an administrative process.

And, in this case, I don't know if the applicant has more information to share on potential -- potential future tenants.

COMMISSIONER RIGGS: No. I have the answer to my question. Thank you.

ACTING CHAIR HARRIS: Thank you, Commissioner Riggs.

Would anyone else like to speak on the EIR?

I have a question. I have some comments on the housing needs' assessment, as well as transportation, TDM and TIA.

And I'm wondering, the information that I've gleaned is from the EIR, especially the appendices. However, most of my comments would refer to items that I would want to be seen in the project. So I'm a little bit unclear as to whether I should discuss them now, or if I should wait until the study session.

PC-18

MR. HOGAN: Madam Chair, based upon what you've told me, it sounds like it's more related to the project design than to the Environmental Impact Report.

The City's Settlement Agreement with the City of East Palo Alto required that population and housing and transportation both be addressed in the EIR. And the

Housing Need Assessment prepared by KMA is the source document for evaluating those issues, specifically at the request of the City of East Palo Alto.

So as I understand it, the document has been prepared, consistent with all the other documents. If you feel that the project should be adjusted or modified in some way, that I would suggest, that may come under the study session.

If your comments relate to the analysis in the EIR, then I think that would be best addressed now.

I hope that answers my -- answers your question.

ACTING CHAIR HARRIS: Thank you. I'll -- you know what? I will wait until the study session for some of these comments.

MR. HOGAN: Okay.

ACTING CHAIR HARRIS: Does anyone else have any comments on the Draft EIR?

Okay. It seems that we, as a Commission, don't have other comments on the Draft EIR. So I think we can close that portion of tonight's session and move on to G1, which is the study session.

(Whereupon, Agenda Item F2 completed.)

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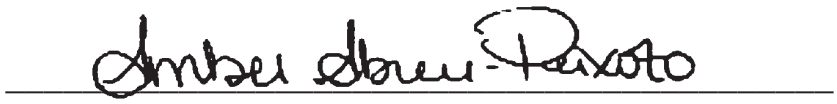
CERTIFICATE OF REPORTER

I, AMBER ABREU-PEIXOTO, hereby certify that the foregoing was taken in shorthand by me, a Certified Shorthand Reporter of the State of California, and was thereafter transcribed into typewriting, and that the foregoing transcript constitutes a full, true, and correct report of said proceedings which took place;

That I am a disinterested person to the said action.

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of May, 2023.



AMBER ABREU-PEIXOTO, CSR No. 13546

Appendix 2

New Draft EIR Appendix 2-1, Biosafety White Paper Memo

MONCHAMP MELDRUM LLP

June 5, 2023

Via email

Payal Bhagat
701 Laurel Street
Menlo Park, CA 94025

RE: Biosafety Comments on the 1125 O'Brien Project Draft EIR

Dear Ms. Bhagat

We are writing in response to the comments received on the 1125 O'Brien Drive Project (Proposed Project) Draft EIR (DEIR) regarding the Biosafety Levels (BSL) of laboratories in the Proposed Project. Under separate cover (and attached here), Tarlton Properties, Inc. (TPI) commissioned and has provided a white paper analyzing the many layers of regulation that cover biosafety for laboratory uses in the Life Science (LS) District. This white paper was prepared by Patricia Beach of Harris & Lee Environmental Sciences. Ms. Beach is a Certified Industrial Hygienist with an extensive background in laboratory biosafety and is the Managing Partner and Principal Consultant for Harris & Lee Environmental Sciences.

BSL – Hazard Impacts

The overlapping layers of federal, state, and local regulation were previously identified and analyzed in the ConnectMenlo EIR from which the Project EIR is tiered. (ConnectMenlo EIR, 4.7-1 – 30). Permissible laboratory uses in the LS District have not changed since that time, and the Proposed Project is entirely consistent with the planning and zoning for the property, including for laboratory uses. (See, e.g., 1125 O'Brien Drive Project Initial Study (Initial Study) at 3-97. The Initial Study is included in the DEIR as Appendix 1-1 and summarized at ES-2.) As such, comments did not raise any new information or identify a more significant impact than those identified in the ConnectMenlo EIR or DEIR. But it is valuable to summarize that information again for the public in the Final EIR, and we suggest Ms. Beach's white paper as a valuable resource for understanding this layered issue.

Additionally, commenters asked about the applicability of the National Institute of Health (NIH) Guidelines. As described in the white paper and ConnectMenlo EIR, there is a robust regulatory scheme in place in California and in Menlo Park that covers all laboratories; it was on this basis that the ConnectMenlo EIR concluded that laboratory uses would be less than significant with application of existing regulation (ConnectMenlo EIR, at 4.7-21, -23, -24). Specific to NIH Guidelines; the NIH produced the guidelines for labs that receive federal funding which can include private laboratories. California has its own regulatory requirements that are required of all labs, the Project's compliance with that regulation is the basis for the less than significant finding in the ConnectMenlo EIR and DEIR which has not changed since the ConnectMenlo EIR.

That said, it is standard industry practice to follow NIH Guidelines where they are relevant for overlapping security. So, for the purpose of a conservative approach and assurance to the public that all relevant safety protocols are in place, we suggest that the following mitigation be added to the EIR:

> Require laboratory uses in the project that are BSL-3 or 4 to undergo third-party certification and commissioning by or under the supervision of a qualified Certified Industrial Hygienist (CIH) with demonstrated practice in biosafety, Registered Biosafety Professional (RBP), or Certified Biosafety Professional (CBSP). A commissioning plan from the qualified certifying agent shall be submitted with the application for administrative permit for the laboratory, and certification and evidence of commissioning shall be submitted to the City as a condition of occupancy and annually thereafter. Certification shall document that the laboratory would meet with all required federal, state, and local standards including Title 8 of the California Code of Regulations, as well as meet relevant Biosafety in Microbiological and Biomedical Laboratories (BMBL) and/or National Institute of Health (NIH) guidelines.

BSL – Noise Impacts

Regarding comments about rooftop noise related to mechanical equipment for labs above BSL 2: The mechanical systems for the proposed project were designed for the Proposed Project's expected uses, which are BSL 1 or 2 laboratories. The proposed mechanical system is described in the October 4, 2022 All-Electric Feasibility Analysis by Western Allied Mechanical, and mechanical system noise was analyzed by Vibrasure in its June 13, 2021 Rooftop Equipment Noise Analysis, both of which are included in the EIR (DEIR Appendices 3-3, 3-4.) Operational noise for the Proposed Project, including rooftop mechanical equipment is analyzed in the DEIR at 4.3-29 – 34 and is found to be less than significant with required mitigation.

The design team has reviewed the mechanical requirements for laboratories above BSL 2, which include additional filtration and decontamination requirements. BSL 3 (or 4) labs are typically very small, and it is possible that the existing mechanical could be used for a small lab above BSL 2 without adding mechanical capacity. There would be no change in noise impacts

for such a design. Although a larger lab above BSL 2 could require additional mechanical capacity, CEQA requires that noise impacts from changed mechanical equipment would need to be within the scope of what was studied in the EIR. Further, the City's Zoning Ordinance limits noise from any rooftop mechanical equipment to 50 dB at 50' (Menlo Park Municipal Code § 16.08.095), which would bar additional noise impacts from any changes to the Proposed Project's mechanical design. For a conservative approach, we suggest that the following mitigation measure be added which clarifies CEQA's requirement:

> Administrative permit application for any BSL 3 or 4 laboratory uses must include either documentation confirming that the existing mechanical/HVAC equipment will provide adequate capacity to satisfy regulatory requirements or details of any new required mechanical/HVAC equipment along with noise analysis for that new equipment and any noise buffering demonstrating that operational noise levels will still meets all noise thresholds in the EIR.

Comments Related to BSL Levels Are Not New Information

As noted above, the Draft EIR for the Proposed Project is tiered from the EIR for ConnectMenlo, which is incorporated by reference. (See, e.g., Initial Study, at 1-2; DEIR at 1-4.) In the ConnectMenlo EIR, the City determined that laboratory uses in the LS District would have less than significant impacts with compliance with the existing regulatory scheme. (ConnectMenlo EIR at 4.7-21, -23, -24.) Analysis of the Proposed Project incorporates this analysis, and confirms it with regard to the Proposed Project. (DEIR at 1-4; IS at 3-97.) Likewise, the DEIR concludes that operational noise impacts for the Proposed Project would be less than significant with required mitigation. (DEIR at 3-34.)

CEQA requires recirculation of an EIR only where a comment identifies new information that would result in a new significant impact that was not included in the EIR, and no mitigation measures are adopted to reduce that impact to a less than significant level. (Pub. Res. Code § 21092.1; CEQA Guidelines § 15088.5.) Recirculation of an EIR for a second round of public review is intended to be an exception to CEQA's comment period on a draft EIR. (*Laurel Heights Improvement Ass'n v Regents of Univ. of Cal.* (1993) 6 Cal.4th 1112, 1132.)

As applied here, public comment regarding laboratory impacts are not new information within the meaning of CEQA, nor are responses to those comments. Analysis of laboratory use in the LS District was included in ConnectMenlo EIR, which is incorporated by reference into the Proposed Project EIR and so included there as if written in full. (CEQA Guidelines § 15150.) The comments do not identify Proposed Project impacts beyond what was studied, since laboratory uses in the Proposed Project are consistent with the planning and zoning for the property. Noise levels for rooftop mechanical equipment for the Proposed Project were likewise studied in the DEIR, and any changes to the Proposed Project would need to comply with the City's

noise ordinance and be within the scope of the EIR. Recirculation of the DEIR therefore would not serve a legitimate CEQA purpose, and is not warranted by comments on the DEIR.

The suggested mitigation included in this letter is provided as an extra layer of assurance for the Planning Commission and public that the Proposed Project would be operated in a safe and responsible manner by ensuring that the Project's compliance with existing regulation is demonstrated and enforceable.

Sincerely,

Rob Taboada

Santa Rosa
(707) 571-8961

San Francisco
(415) 287-0056

Harris & Lee Environmental Sciences, LLC

Ron Krietemeyer
Chief Operating Officer
Tarlton Properties, Inc.
1530 O'Brien Drive, Suite C
Menlo Park, CA 94025

May 31, 2023

RE: Biosafety for R&D Development in Menlo Park's Life Sciences District

Dear Ron,

Thank you for the opportunity to provide this White Paper to explain the current status of the biosafety practices and regulatory framework in the San Francisco Bay Area, including San Mateo County ("SMC"). The White Paper is intended to present the state of current regulatory oversight of biosafety in general, as well as provide a view of actual practice within the private sector of biopharmaceutical operations.

I have worked in the private biopharmaceutical business sector for 24 years. From 1999 to mid-2006, I was the Associate Director of Occupational Safety and Industrial Hygiene in the Environmental Health & Safety ("EHS") department for the former Chiron Corp, a multinational R&D and manufacturing company making several biologically-derived drugs (Chiron was fully absorbed by Novartis in 2006). Chiron's headquarters site, in Emeryville, CA, operated a BSL-3 laboratory. For the last 17 years, I and my team of consultants have been providing EHS support services to the private biopharmaceutical business sector. We work in all size companies from start-ups to large R&D and commercial manufacturing operations. The vast majority of our work in this sector is based in SMC where we have dozens of biopharmaceutical clients. In addition, we have clients in Alameda County, the City and County of San Francisco, Santa Clara County, and more. The attached White Paper is a summary of my knowledge and experience in this industry.

Sincerely,

Patricia Beach

Patricia Beach, MS, CIH
Managing Partner/Principal Consultant
Harris & Lee Environmental Sciences, LLC

Introduction

The use of hazardous chemicals and the generation of chemically hazardous waste is regulated through multiple layers at federal, state and local levels and more well-known to the lay public. The framework and work practices for the safe use and disposal of biologically-derived materials is less understood. This white paper addresses the regulatory framework, industry standard guidelines, and real-world practices pertaining to the use of biological organisms and their products (including synthetic and recombinant biologic materials) in California, with a focus on the San Francisco Bay Area.

History of Biosafety in the United States

Naturally-occurring bacteria, viruses, molds, yeasts, toxins (which are produced by plants, molds, bacteria) are all around us. Collectively these are referred to commonly as micro-organisms, biologic materials and/or biohazards. Considerable research and development (R&D) occurred and continues to occur with microorganisms and materials derived from microorganisms. As a result, drugs, vaccines, and life-saving treatments are available for many diseases either caused by microorganisms directly (e.g., antibiotics, and flu, covid and hepatitis vaccines) or use of biologic products to develop new drugs (e.g., Herceptin for breast cancer treatment, Rituxan for non-Hodgkin's lymphoma, and many more).

With regard to naturally occurring micro-organisms, and their use in research in laboratory settings, the Center for Disease Control and Prevention (CDC) provides a wealth of information and guidance in its Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition (CDC, 2020). The BMBL was first published in 1984 and quickly became the cornerstone for biosafety practice and policy in the U.S. Also in 1984, the Association for Biosafety and Biosecurity (ABSA International) was founded. ABSA International promotes biosafety as a scientific discipline and serves the growing needs of biosafety professionals throughout the world.

The concerns for community exposure through the release of altered bio-organisms from research labs emerged as a unique public health concern in the 1970's when the ability to alter and engineer micro-organism DNA, by either recombinant or synthetic means[1] (referred to as rDNA), became more common and use in research spread widely. Biological risk emerged as a serious topic of public concern. The primary concern was then, and still is, the potential for these engineered molecules to combine with naturally-occurring DNA in either humans, animals or the natural environment to cause unknown harm. As a result of this emerging risk, the National Institutes of Health (NIH) published the first Guidelines for Recombinant DNA Research in June 1976. The Guidelines are

[1] According to NIH (NIH, 2019), recombinant and synthetic nucleic acids (DNA and RNA) are defined as follows: a) Recombinant -- molecules that are constructed by joining nucleic acid molecules (from different organisms, most often) and that can replicate in a living cell; and Synthetic – molecules that are chemically or by other means synthesized or amplified, and can base-pair with naturally occurring nucleic acid molecules. Lastly, molecules that result from the replication of either recombinant or synthesized DNA are also included in this class of molecules.

updated regularly and oversight is provided by the NIH's Recombinant DNA Advisory Committee or RAC. The R&D activities surrounding altered and engineered DNA in microorganisms has been the driver of many of the modern life-saving treatments and production of drugs within the biotechnology and biopharmaceutical industry.

In the U.S., the BMBL and the NIH Guidelines go hand-in-hand as the standards of practice for exposure control for both workers and the public when it comes to managing biosafety and biosecurity in research operations. Both documents address the biohazards and controls for Biosafety Levels 1 through 4, described below. The BMBL and the NIH Guidelines were developed, and are updated regularly, in collaboration with a broad range of scientists, laboratory directors, occupational physicians, epidemiologists, public health officials and health and safety professionals (CDC 2020) in order to continually address the changing nature of biosafety due to emerging threats and changing research. These documents define the work practices, containment, facility design requirements and the program management, oversight and training that define the standard of accepted practice for biosafety.

Regulatory Framework for Biosafety in the United States

Biosafety is regulated at the Federal, State and local levels of government. Because the use of biologicals in R&D and commercial products is newer than the use of chemicals, the regulatory framework, while robust, is less apparent than for chemicals. The table below summarizes the regulatory framework with a more detailed discussion of each government level to follow.

Government Level	Legal Requirement	Biosafety Level	Industry Standard Practice
Federal Government	OSHA BBP Standard (29 CFR 1910.1030)	BSL 1, 2	CDC BMBL
	NIH Guidelines for rDNA Research[a]	BSL 1,2,3,4	NIH Guidelines for rDNA Research[a]
	Federal Select Agent Program (FSAP) (42 CFR 73; 7 CFR 331 and 9 CFR 21)	BSL 1,2,3,4	
	US Department of Transportation (DOT), 49 CFR.	BSL 1,2,3,4	
California State	Cal/OSHA BBP Standard (8 CCR § 5193)	BSL 1, 2	CDC BMBL
	Cal/OSHA ATD Standard (8 CCR § 5199)	BSL 3, 4	NIH Guidelines for rDNA Research[a]

Government Level	Legal Requirement	Biosafety Level	Industry Standard Practice
	Medical Waste Management Act (California Health and Safety Code. Sections 117600 – 118360)	BSL 1,2,3,4	
	NIH Guidelines for recombinant DNA Research[a]	BSL 1,2,3,4	
Local Government (San Mateo County)	Permit to generate Medical Waste; enforces the Medical Waste Management Act requirements	BSL 1,2,3,4	CDC BMBL
	Lab Decommissioning requirements	BSL 1,2,3,4	NIH Guidelines for rDNA Research[a]

[a] The NIH Guidelines for rDNA Research are legally required if an entity (public or private) receives funding from NIH for any aspect of its research, directly or indirectly. In the absence of funding, the NIH Guidelines, in whole or as applicable, are routinely followed as a matter of standard business practice.

Federal Requirements

Federal OSHA regulates workplace exposures to Bloodborne Pathogens (BBP) under the Bloodborne Pathogens Standard (29 CFR 1910.1030). BBP are infectious agents present in blood and body fluids and/or tissues of humans and non-human primates. It is applicable to all workplaces where the potential for exposure to BBP exists, including, but not limited to, medical and dental facilities, as well as laboratories who conduct research with BBPs. The BBP Standard was revised in 2000 to incorporate the hazard control and reporting of needlesticks from syringes and other BBP-contaminated sharps (i.e., razor blades, broken glass, etc).

Note: States may have their own OSHA regulatory framework as long as it is approved by Federal OSHA and is at least as strict as the Federal Standards. Workplace safety and health in California is promulgated in the Cal/OSHA regulations (Title 8 of the California Code of Regulations, 8CCR). Additional details are provided below pertaining to biohazard control at the State level.

The Federal Select Agent Program (FSAP) is part of the CDC and the U.S. Department of Agriculture (USDA). The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. Select agents are listed by name in the FSAP regulations. The FSAP does the following in regards to select agents:

- Develop, implement and enforce select agent regulations;

- Maintain a national database;
- Inspect entities that possess, use or transfer select agents;
- Ensure individuals who work with select agents receive a security threat assessment, as required;
- Provide guidance to regulated entities on achieving compliance. The FSAP regulations reference the CDC BMBL and the NIH Guidelines as the primary resources for compliance with the FSAP.

The NIH Guidelines are required to be followed when an institution, including any collaborating institutions either private or public, receives Federal money from NIH to conduct research as defined in the Guidelines. In this case, many private R&D operations (including biopharmaceutical companies in the SF Bay Area) are required to follow the NIH Guidelines as a condition of receiving such funding (either directly or indirectly). Where not required through receipt of federal funds, NIH Guidelines are generally followed, as applicable, as standard industry practice.

Lastly, the transport by air, rail and roadways, of infectious and non-infectious biologic materials (as well as hazardous chemicals) is governed by the U.S. Department of Transportation.

California Requirements

California regulates workplace exposure to BBP, similar to Federal, above, under its BBP Regulations (8 CCR § 5193 et seq.). The BBP Standard addresses workplace hazards in affected work populations by requiring (in summary):

- A written BBP Program;
- Training of affected employees initially at hire and annually thereafter;
- Offering affected employees a Hepatitis B vaccination;
- Maintenance of a Sharps Injury Log; and
- Review and update of the Program to ensure it remains relevant to site operations;
- Lab facilities and handling practices consistent with BSL-2 controls described in the BMBL.

The BBP Standard emphasizes potential exposures via aerosol droplet transmission by inadvertent contact with mucous membranes, and accidental exposure via needlesticks.

In addition to the BBP Standard, California is unique in that is also regulates the potential exposure to Airborne Transmissible Disease (ATD) and Airborne Transmissible Pathogens (ATPs) in workplaces under is ATD Standard (8 CCR § 5199). ATDs and ATPs are specifically listed by name in Appendix A of the Standard. In addition to clinical settings and other impacted worksites (mortuaries, jails, etc.) there are specific requirements for laboratories conducting research on airborne pathogens and microorganisms. The ATD Standard defines an ATP-L (Airborne Transmissible Pathogen – Laboratory), as follows:

A pathogen that meets one of the following criteria: (1) the pathogen appears on the list in Appendix D, (2) the Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends biosafety level 3 or above for the pathogen, (3) the biological safety officer recommends biosafety level 3 or above for the pathogen, or (4) the pathogen is a novel or unknown pathogen.

Simply put, the inclusion of the BMBL by reference in 8 CCR § 5199, and the reference to a biological safety officer (BSO), which is defined in the regulation, makes the presence of any BSL-3 laboratory in California subject to the additional regulatory requirements of Cal/OSHA under the ATD Standard. In addition, if the laboratory receives funding directly or indirectly from NIH, the laboratory is also subject the NIH Guidelines.

Finally, biologically infectious and/or medical waste ("red bag waste") is regulated by the Medical Waste Management Act (California Health and Safety Code. Sections 117600 – 118360) overseen by the California Department of Public Health (CDPH). Any laboratory that handles BBP or other biohazards generates red bag waste and is therefore subject to Medical Waste Management Act. The CDPH extends authority to local agencies (most commonly County level government agencies, such as SMC) for the oversight and enforcement of the Medical Waste Management Act.

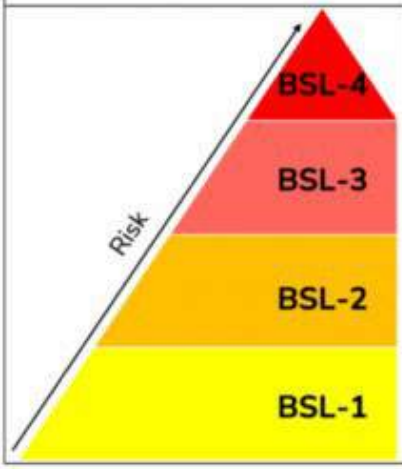
Local Requirements

In Menlo Park, the SMC Department of Environmental Health oversees the waste generation from biological research by requiring the filing of a Medical Waste Permit pursuant the amount of biological waste that a site produces (<200 kg/month = Small Quantity Generator, or SQG; >200 kg/month = Large Quantity Generator, or LQG). SMC staff inspects each facility that files a permit at initiation of operations and generally annually or semi-annually thereafter.

SMC also manages the safe closure of laboratories that conduct biological research with their medical waste closure plan requirement. In order to safely close an active permit, a closure plan must be submitted that documents the microorganisms in use, the facility decontamination protocols to be followed and record of completion of such protocols. The SMC Facility Closure Requirements are presented in Attachment 1.

A Review of the Biosafety Levels

According to the BMBL (2020), the CDC published *Classification of Etiologic Agents on the Basis of Hazard* in 1974. This report introduced the concept for establishing ascending levels of containment that correspond to risks associated with the handling of infectious microorganisms that present similar hazard characteristics. Human pathogens were grouped into four classes according to mode of transmission and the severity of disease they caused. These became known as the Biosafety Levels (BSLs). The primary risk criteria used to define the four ascending levels of containment (the BSLs 1 through 4), are infectivity, severity of disease, transmissibility, and the nature of the work being conducted (CDC 2020). See the Figure below.

Biosafety Level (BSL)	Characteristics	Pathogens/Disease
	Infectious aerosol transmission that may cause serious or lethal infections with no treatment available	Ebola virus, Variola virus (smallpox), Marburg virus
	Infectious aerosol transmission that may cause serious or lethal infections	Coronavirus, Mycobacterium tuberculosis, Yersinia pestis (plague), malaria
	Infectious agents of moderate risk with ingestion or mucous membrane transmission	Influenza, Lyme disease, salmonella, measles, mumps
	Low-risk agents that are not known to cause human disease	E. coli

Each level of containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling the agent. The facility safeguards associated with the BSLs help protect non-laboratory occupants of the facility, the public health and the environment (CDC 2020). Summaries of the biosafety levels (BSLs) 1 through 4 are provided below. The California BBP Standard essentially addresses laboratory practices and facilities described in BSL-1 and BSL-2. The California ATD Standard directly addresses the laboratory practices and facilities described in BSL-3 and BSL-4.

A summary table from the BMBL and a more detailed infographic showing facility safeguards of the four BSLs are provided in Attachment 2.

Biosafety Level 1

- Used for bioagents not known to consistently cause disease in healthy adults.
- Standard microbiological laboratory practices, such as:
  - All workers receive appropriate training;
  - Work surfaces decontaminated once a day and after spill;
  - Eating, drinking, smoking and applying cosmetics are prohibited in the laboratory;
  - Procedures are performed carefully to minimize creation of aerosols;
  - A sink for handwashing is available.
- Laboratory Facilities include sturdy furniture that is easily cleanable, and if the lab has windows, they are fitted with fly screens.
- Examples: high school or college labs and research institutions

Biosafety Level 2

- Used for a broad spectrum of bioagents in the community and associated with human disease of moderate severity.

- Standard microbiological laboratory practices as BSL-1, plus:
    - All contaminated liquid or solid waste is decontaminated before disposal;
    - Access to the laboratory is limited to qualified and trained personnel;
    - BSL-2 labs are labeled as such and the biologics in use are indicated;
    - PPE is worn in the lab (lab coat, disposable gloves, safety glasses) and PPE is removed upon lab exit;
    - Special care is used with sharps to avoid accidental punctures;
    - Durable, leakproof containers are used to collect waste that is decontaminated offsite;
    - Workers are offered medical surveillance (prophylaxis and vaccines, if available) and encouraged to self-report any health conditions that could make them more susceptible to infection.
- Laboratory Facilities same as BSL-1, plus:
    - Limited access and lab is separated from public areas
    - A biological safety cabinet (BSC) is used to enclose tasks that have the risk of generating aerosols;
    - An eyewash is available at a lab sink;
    - A method for decontaminating laboratory waste is available.
- Examples: research institutions, essentially all hospitals and medical and veterinary schools, dental offices and medical laboratories.

Biosafety Level 3

- Used for bioagents with potential for aerosol transmission that may cause serious or potentially lethal disease by inhalation if left untreated.
- Workers are immunized for agents handled or potentially present.
- Standard microbiological laboratory practices as BSL-2, plus:
    - Any incidents resulting in exposures are immediately reported to lab supervisor and institutional management and investigated. Appropriate records are maintained.
    - Use of respiratory protection is considered based on risk assessment;
- Laboratory Facilities same as BSL-2, plus:
    - Access to the lab is through two consecutive self-closing doors, typically separated by a change room and/or anteroom.
    - The handwashing sink is hands-free or automatically operated and should be located near the exit door;
    - A mechanical air ventilation system is required that provides sustained directional airflow by drawing air into the lab from “clean” areas toward potentially contaminated (e.g., negative air cascade). The design is such that under failure conditions the airflow will not be reversed at the containment barrier;
    - A visual monitoring device that confirms directional airflow is provided;
    - Lab exhaust air is not recirculated;
    - Lab exhaust air is dispersed away from occupied areas from the building air intake locations, or the exhaust air is HEPA filtered.
    - When present, HEPA filter housings have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out capability;

    - BSL-3 facility design, operational parameters, and procedures are verified and documented prior to operation. Facilities are tested annually or after significant modification to ensure operational parameters are met;
    - Appropriate communication systems are provided between th lab and the outside;
    - Provision for emergency communication and emergency access or egress are developed and implemented.
- Examples: biological research institutions, hospitals and medical and veterinary schools.

Biosafety Level 4

- Used for dangerous and exotic bio-agents that pose a high risk of life-threatening disease for which there is no available vaccine or therapy.
- This is the highest level of containment for biological organisms and have controls and facility requirements far beyond BSL-3. There are two types of BSL-4:
    - Cabinet laboratory: manipulation of agents is performed in a Class III BSC (which is an entirely enclosed glovebox); and
    - Suit Laboratory: personnel wear a positive-pressure supplied-air protective suit.
- Standard microbiological laboratory practices as BSL-3, plus:
    - Any materials leaving the BSL-4 lab (such as for ultimate disposal), are passed through a disinfectant dunk tank, fumigation chamber or decontamination shower.
    - Entry and exit of personnel is maintained in a logbook or other means of documenting;
    - An inventory system for agents stored in the lab is in place;
    - Only approved laboratory clothing is worn (all jewelry is removed – eyeglasses are allowed) into the lab. All personnel leaving the lab take a personal body shower (the degown room must be equipped with a shower);
- Laboratory Facilities same as BSL-3, plus (not all-inclusive):
    - Detailed requirements for BSC-IIIs for cabinet BSL-4 labs.
    - Cabinet or suit BSL-4 can be located in it's own separate building, or a clearly demarcated and isolated zone within a building (a dedicated, non-recircuilating ventilation system that serves the BSL-4 lab)
    - Central vacuum systems are discouraged; if present it does not serve areas outside the lab.
    - Walls, floors, and ceilings of the lab are constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion.
    - Backflow prevention devices (two in series) are in place to ensure that no plumbing or other services backflow form the BSL-4 lab. Breathing air systems are exempt from this provision.
    - Windows are break-resistant and sealed.
- Examples: There are only four operational BSL-4 labs in the U.S., according to the NIAID (National Institute for Allergy and Infectious Disease) website.

Summary

The frameworks for biological safety are robust in the United States and particularly in California and the Bay Area. Research scientists in the private sector, who invariably come from research institutions where NIH-funding grants are common-place, are very familiar with the NIH Guidelines and the BMBL which are standard industry practice. Further, Environmental Health and Safety (EHS) Professionals and Biological Safety Officers (BSOs) that support the exposure controls and overall risk management within the institutions and companies (both publicly funded and privately owned) use the BMBL and the NIH Guidelines as the "go-to" resources for managing biological exposure risk, in conjunction with other workplace regulations such as Cal/OSHA and local government enforcement. Finally, here in California, we are unique in that the BMBL is referred to as the citing reference for BSL-3 work in laboratories. This regulation gives the recommendations in the BMBL the force of law in California where BSL-3 work is done.

References

California Occupational Safety & Health Administration (Cal/OSHA).

Centers for Disease Control (CDC). National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition. June 2020.

National Institutes of Health (NIH), Dept. of Health and Human Services. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. April 2019.

San Mateo County (SMC) Medical Waste Program.
https://www.smchealth.org/medwaste

ATTACHMENT 1
San Mateo County Biological Lab Decommissioning Requirements

SAN MATEO COUNTY HEALTH
ENVIRONMENTAL HEALTH SERVICES

Environmental Health Services
Medical Waste Program
2000 Alameda de las Pulgas, Suite #100
San Mateo, CA 94403
Phone:(650) 372-6200 | Fax: (650) 627-8244
smchealth.org/medwaste

MEDICAL WASTE PROGRAM
Facility Closure Requirements

DEFINITIONS:

Active Work Areas: Locations, rooms, or labs within the business where infectious agents are stored, used, or generated during operations. This includes BSL 1 areas.

Infectious Agents: (HSC§ 117675) A type of microorganism, bacteria, mold, parasite, or virus, including, but not limited to, organisms managed as Biosafety Level II, III, or IV by the federal Centers for Disease Control and Prevention, that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

Sanitizing Agent: A chemical agent as specified in HSC§ 118295.

REQUIREMENTS:

San Mateo County requires businesses with County medical waste permits to carry out their due diligence and perform an appropriate facility closure. Businesses must demonstrate to the County that they have properly disposed of all of the medical waste that they have generated, removed all infectious agents and equipment, and decontaminated all surfaces contaminated with infectious agents. A formal closure must be done when the business is either vacating the location, a partial portion of the facility is being vacated or given back to the property owner, or if a process involving biohazardous waste has been discontinued.

Businesses with medical waste permits are categorized into one of three Tiers based upon their original registration application and/or periodic inspections. Each business Tier has different criteria to successfully perform a closure, meet the County closure requirements, and thus formally terminate their County permit. Each level will be required to demonstrate that they appropriately decontaminated all areas at the business where medical waste and infectious agents were generated, handled or stored. Decontamination of these areas must be commensurate with the infectious agents they utilized.

A pre-closure walkthrough may be requested by facility representatives. The County Inspector shall make every effort to accommodate these requests. During the pre-closure meeting/walkthrough the County Inspector will outline the County closure requirements for the business, walk the facility, and identify any unique closure aspects to be addressed.

REQUIRED CLOSURE PROCEDURES FOR TIER I BUSINESSES:

1. Business notifies County in writing 30 days prior to closure. Labeled photographs of all active work areas must be submitted to the County at time of notification.

2. Business decontaminates all active work area surfaces, with the appropriate sanitizing agent.

3. Business submits labeled photos of active work areas after closure activities have been successfully completed along with copies of last medical waste shipment tracking documents.

Rev. 07/03/2019

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REQUIRED CLOSURE PROCEDURES FOR TIER II BUSINESSES:

1. Business notifies County in writing 30 days prior to closure.

2. Business submits a written "Closure Work Plan" as described below in Tier III requirements, or they may use the County Closure Work Plan Form.

3. Business must submit of copies of last medical waste shipment tracking documents.

4. Business schedules a mandatory final closure walkthrough with the County Medical Waste Inspector (County Inspector).

REQUIRED CLOSURE PROCEDURES FOR TIER III BUSINESSES:

Business must provide to the County a full written closure work plan within 30 days prior to the closure.

Closure Work Plan required components:

- Scope of Work: Outline the proposed areas to be decontaminated, process of decontamination and sanitizing agent(s) used, and disposition of all infectious equipment, products, and wastes. Also include disposition of anything to be left behind (e.g. fume hoods, bio safety cabinets,

- Proposed Schedule: Provide a schedule for activities to be performed during the closure. A 72- hour notice to the County Inspector is required for any oversight at various phases of closure (e.g. witnessing of sampling, special site decontamination, etc.).

- Project Management Team: Identify staff and qualifications (e.g. all licenses, training certifications, certificates of insurance). List project managers and emergency coordinators who will be available during closure and cleanup of the site. Include a 24-hour phone number for emergency coordinators.

- Map(s): (e.g. with notations of hot spots or special cases). Provide maps identifying all historic storage locations of infectious agents and all waste storage areas (e.g. current and historic).

- Proposed Subcontractors: (if not known, state this, but you must send in their qualifications, training plan, safety plan, certificates of insurance, management teams, and operational procedures prior to their mobilization onsite).

- Health and Safety Plan: Provide a Health and Safety Plan that outlines specific hazards and protective measures to be used during the closure activities at the facility, including security and access. Site closure activities must be conducted by employees with adequate training per CAL/OSHA regulations outlined in Title 8, CCR and 29 CFR, part 1910.1030.

- Decontamination Procedures: Describe the procedures for surface and equipment decontamination, rinseate collection, and disposal. Decontamination shall include all potentially contaminated surfaces, equipment, drain systems, and areas of the facility where medical wastes and infectious agents contact was likely to have occurred. A narrative of your decontamination methodology, including sanitizing agents used must be provided.

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- Additionally if the facility treated medical waste onsite, they must follow and address the regulations found in HSC Code 118155(e). These additional requirements must be included in their Closure Work Plan.

The Closure Work Plan must be reviewed and approved by a County Inspector before work is started. If you are also closing a CUPA permit and submitting a Closure Plan to your CUPA inspector, you may include or insert these closure documentation requirements in one plan submitted to both CUPA and the Medical Waste Program. Please copy both your County Inspectors on all correspondences.

POST CLOSURE:

After the closure is complete you are required to submit a final closure report. This report should include:

- All final medical waste tracking documents
- A narrative of the final decontamination methodology. (i.e. what did you do?)
- Copies of all decontamination certificates
- Map of areas cleaned
- Disposition of fixed biohazardous assets and equipment left behind at the facility
- Disposition of biohazardous equipment moved, transferred or sold
- Any testing results reports
- Forwarding address and contact information

Once you have completed your closure activities and all of the medical waste generated has been removed, you must contact your County Inspector to arrange a final closure walkthrough. A minimum notification of 48 hours is required for a closure walkthrough.

During the final closure walkthrough the County Inspector shall perform a thorough walk around of the facility in order to gather information to validate that the closure plan was followed and completed. This walkthrough and its observations will be documented on an observation inspection report documenting that the County medical waste closure requirements have been met. Any health violations or deviations from the proposed/approved Closure Plan will result in a re-inspection and fees billed accordingly.

Once the final report (or other required documentation per Tier) is received, the permit will be closed out.

Note: Non-registered businesses that are closing a facility must follow the same requirements found in this policy. An account will be opened and the facility will be billed for any County Inspector time at the current hourly rate.

Note: If hazardous waste is generated at the site, the CUPA inspector must be notified.

ATTACHMENT 2
Summary of BSLs as provided by the CDC

Table 1. Summary of Laboratory Biosafety Levels (BSLs)

BSL	Agents	Special Practices[a]	Primary Barrier and Personal Protective Equipment[a]	Facilities (Secondary Barriers)[a]
1	Well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment.	Standard microbiological practices	No primary barriers required; protective laboratory clothing; protective face, eyewear, as needed	Laboratory doors; sink for handwashing; laboratory bench; windows fitted with screens; lighting adequate for all activities
2	Agents associated with human disease and pose moderate hazards to personnel and the environment	Limited access; occupational medical services including medical evaluation, surveillance, and treatment, as appropriate; all procedures that may generate an aerosol or splash conducted in a BSC; decontamination process needed for laboratory equipment	BSCs or other primary containment device used for manipulations of agents that may cause splashes or aerosols; protective laboratory clothing; other PPE, including respiratory protection, as needed	Self-closing doors; sink located near exit; windows sealed or fitted with screens; autoclave available
3	Indigenous or exotic agents; may cause serious or potentially lethal disease through the inhalation route of exposure	Access limited to those with need to enter; viable material removed from laboratory in primary and secondary containers; opened only in BSL-3 or ABSL-3 laboratories; all procedures with infectious materials performed in a BSC	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls; two pairs of gloves, when appropriate; protective eyewear, respiratory protection, as needed	Physical separation from access corridors; access through two consecutive self-closing doors; hands-free sink near exit; windows are sealed; ducted air ventilation system with negative airflow into laboratory; autoclave available, preferably in laboratory

Continued on next page ►

BSL	Agents	Special Practices[a]	Primary Barrier and Personal Protective Equipment[a]	Facilities (Secondary Barriers)[a]
4	Dangerous and exotic agents that pose high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that are frequently fatal, for which there are no vaccines or treatments; and related agents with unknown risk of transmission	Clothing change before entry; daily inspections of essential containment and life support systems; all wastes decontaminated prior to removal from laboratory; shower on exit	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls;[b] gloves;[b] full-body, air-supplied, positive-pressure suit[c]	Entry sequence; entry through airlock with airtight doors;[c] walls, floors, ceilings form sealed internal shell; dedicated, non-recirculating ventilation system required; double-door, pass-through autoclave required

a. Each successive BSL contains the recommendations of the preceding level(s) and the criteria in the cell.
b. Applies to Cabinet Laboratory
c. Applies to Suit Laboratory

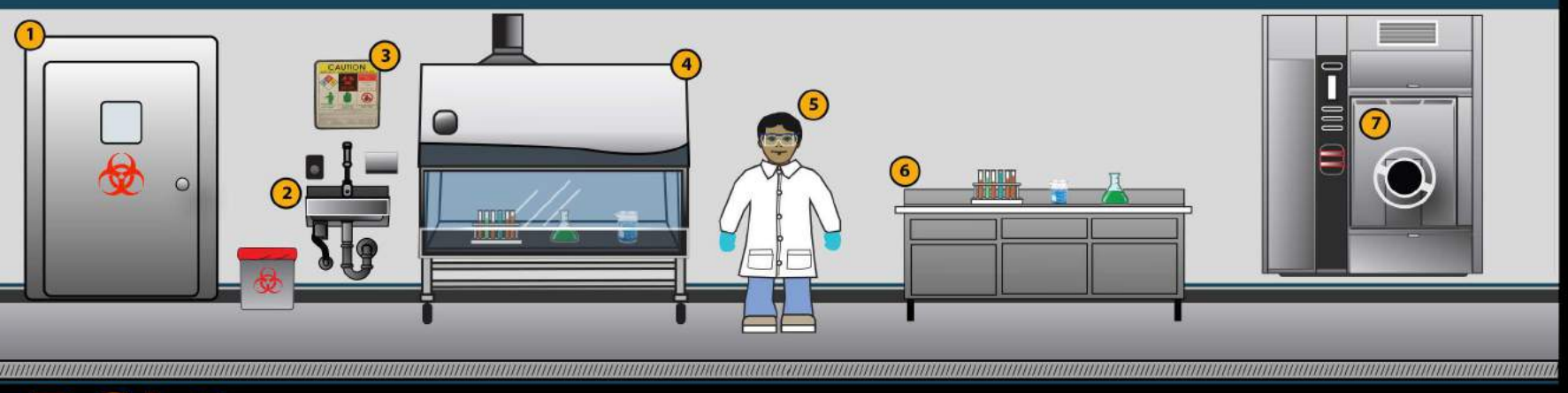
4 BIOSAFETY LAB LEVELS

BSL1

BSL1

1. controlled access
2. hand washing sink
3. sharp hazards warning policy
4. personal protective equipment
5. laboratory bench
6. autoclave

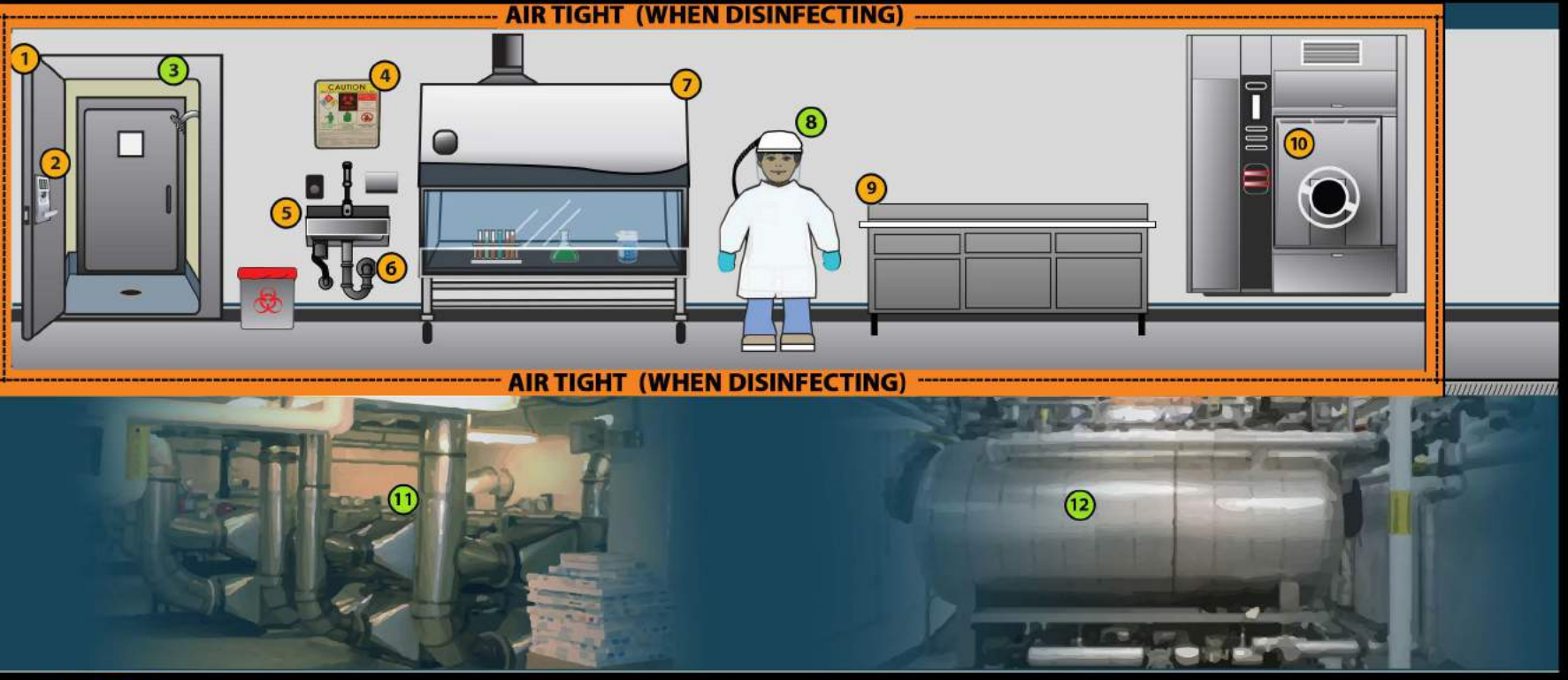
BSL2



BSL2

1. controlled access
2. hand washing sink
3. sharp hazards warning policy
4. physical containment device
5. personal protective equipment
6. laboratory bench
7. autoclave

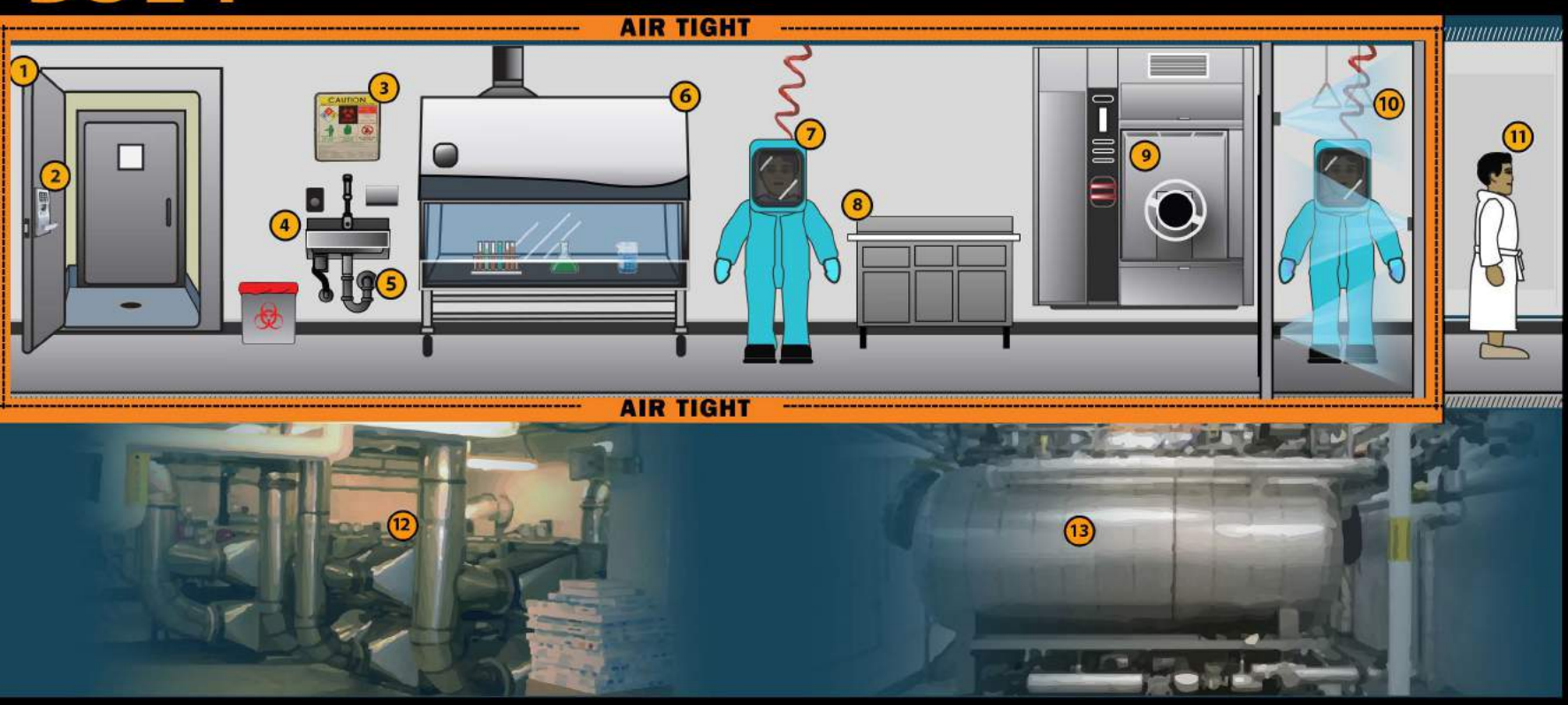
BSL3 (WITH RISK-BASED ENHANCEMENTS)



BSL3

1. self-closing, double-door access
2. controlled access
3. personal shower out
4. sharp hazards warning policy
5. hand washing sink
6. sealed penetrations
7. physical containment device
8. powered air purifying respirator
9. laboratory bench
10. autoclave
11. exhaust HEPA filter
12. effluent decontamination system

BSL4



BSL4

1. self-closing, double-door access
2. controlled access
3. sharp hazards warning policy
4. hand washing sink
5. sealed penetrations
6. physical containment device
7. positive pressure protective suit
8. laboratory bench
9. autoclave
10. chemical shower out
11. personal shower out
12. supply and exhaust HEPA filters
13. effluent decontamination system

Required safety equipment Risk-based enhancements

www.cdc.gov/24-7

Santa Rosa
(707) 571-8961

San Francisco
(415) 287-0056

Harris & Lee Environmental Sciences, LLC

Ron Krietemeyer
Chief Operating Officer
Tarlton Properties, Inc.
1530 O'Brien Drive, Suite C
Menlo Park, CA 94025

July 20, 2023

RE: Supplement to Biosafety for R&D Development in Menlo Park's Life Sciences District

Dear Ron,

Menlo Park has asked for additional information on protocols that would be in place in the event of accidental release. The question has a response in two parts: since the primary goal of biosafety is to prevent accidental release, the first relevant protocols exist to prevent accidental release in the event of building failure (i.e., power or mechanical failure, natural disaster). The second set of relevant protocols explained in the second part of the response relates to preparations that would occur to respond in the event that primary protocols related to preventing release are overcome and an accidental release occurs.

Conditions of approval recommended by TPI would allow the City to confirm this process for any BSL 3 or higher lab, by certification and commissioning performed by an expert in the field, as part of the administrative use permit and/or building permit required for laboratory use.

Protocols in the event of complete building failure (electrical, HVAC)

The first line of defense to protect workers, building occupants, and the environment and community from exposure are the Primary Barriers (Biologic Safety Cabinets or BSCs) and Secondary Barriers (facility design requirements) utilized for biohazardous work. For higher risk operations (BSL-3 and BSL-4) containment requirements increase with the degree of hazard (see Whitepaper and infographic attachment). In operational mode, BSCs and facility design requirements, which must be consistent with Title 8 or the BMBL as appropriate, prevent worker exposure and escape of biohazards contained in labs. In the event of an HVAC and/or complete power failure event, back-up power from the building's emergency power generator would be triggered. In the event of an HVAC and/or complete electrical failure, and if the emergency power generator capacity is exhausted or fails, the Primary and Secondary Barriers of a lab also function as a passive barrier for keeping biohazards inside the building, thereby minimizing the risk of escape of biohazards. Barriers are redundant such that if one barrier fails (i.e., a BSC failure), the next barrier (i.e., a lab facility) would contain that escape to prevent release into the wider building or community.

Protocols for response in the event of accidental release

Biosafety plans are required by Cal/OSHA Bloodborne Pathogens (BSL-1 and 2) and Airborne Transmissible Disease (ATD) regulations (BSL-3 and above), respectively, to be developed to address engineering controls (e.g., BSCs), work practices, personnel protective equipment requirements, disinfection and decontamination requirements, biohazardous waste management and risk management procedures. For BSL-3 and above, the ATD Standard requires the establishment of emergency procedures for "uncontrolled releases within the laboratory and untreated releases outside the laboratory facility, these procedures shall include effective means of reporting such incidents to the local health officer." For the proposed building, the local health officer would be designated by the San Mateo County Department of Environmental Health Services.

Use of Select Agents has additional legal requirement for an emergency and security plan to be submitted to the Federal Government for oversight. Actual handling of select agents is covered under the Biosafety Plans addressed above.

San Mateo County, through its hazardous material business plan and hazardous waste generator permit program, requires that a facility emergency response plan be prepared and made available for review. San Mateo County's Medical Waste Management Plan oversight focuses on proper disposal and leak prevention of medical waste (which includes biohazardous waste), as well as decommissioning oversight for labs that move or go out of business. Finally, all companies with 10 or more employees are required by Cal/OSHA to have a written Emergency Action Plan (T8 § 3220) that ensures employee safety from fire and "other emergencies". Other emergencies would include earthquake, other natural disasters and hazard-specific emergencies including chemical and biological hazard spills, leaks and/or releases. Preparation of an emergency action plan that specifically addresses biohazardous release would be included in the commissioning review for BSL-3 and above labs as part of the administrative use or building permit.

Thank you for the opportunity to address these questions.

Sincerely,

Patricia Beach

Patricia Beach, MS, CIH
Managing Partner/Principal Consultant
Harris & Lee Environmental Sciences, LLC