# Biosafety And Biocontainment Plan

**Purpose or Principle or Introduction**

The purpose of this program is to reduce employee injuries and illnesses as a result of exposure to biohazardous materials. Biohazardous materials and biological materials which may harbor human, or animal pathogens are routinely encountered in this facility. This document provides information to assist in the handling of these biohazards.

**Scope**

This policy is intended for the safe handling and disposal of hazardous biological materials which may consist of infectious agents, as well as substances actually or potentially contaminated with them. Within the SCPMG Lab Care Delivery System, a large number of laboratory staff handles such materials as part of their work routine.

**Policy**

Our activities include laboratory operations where employees perform procedures that may aerosolize ATPs-L. ATPs-L are pathogens that meet any *one* of the following criteria:

1. The pathogen appears on the list in Appendix D of title 8 CCR 5199.
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.
4. The pathogen is a novel or unknown pathogen.

Due to this exposure, we are required to establish and implement a written Biosafety Plan that meets the requirements of title 8 CCR 5199.

☐ Our employees do not have direct contact with ATD cases, suspected cases of ATD, or with potentially infected cadavers. Therefore, we are only required to comply with the provisions of subsection (a), subsection (f), all provisions of title 8 CCR 5199 referred to in subsection (f), subsection (i), and subsection (j) and maintain this written Biosafety Plan for Laboratories.

☒ Our employees have direct contact with ATD cases, suspected cases of ATD, or with potentially infected cadavers and, therefore, we also protect them by following the requirements of the other subsections of title 8 CCR 5199, including a written Exposure Control Plan, engineering controls, respiratory protection, medical services, training, and recordkeeping.

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## Biosafety And Biocontainment Plan, *continued*

**Designation of the Biological Safety Officer**

The Southern California Permanente Medical Group (SCPMG) Lab Care Delivery System has designated a Biological Safety Officer to be in charge of implementing and overseeing this Biosafety Plan. A biosafety Officer must be an individual who is qualified by training and experience in biosafety protection and in safe use and disposal of biohazardous material.

The Biosafety Officer is responsible for:

- Development of a comprehensive Biosafety Program
- Review of the program at least annually
- Ensure requirements are met
- Ensure control measures are utilized
- Perform risk assessments and job task analysis
- Perform audits and compile reports of findings
- Provide meaningful biosafety training
- Maintain documentation and recordkeeping
- Manage emergency response activities
- Ensure adherence to Select Agent Program requirements
- Monitor DOT regulatory compliance and transport of materials
- Establish Standard Operating Procedures (SOPs)

The designated Biosafety Officer (BSO) for the RRL is:

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| Princess Vergara | Director, Environmental Health & Safety |

The designated Assistant Biosafety Officer (ABSO) is:

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|---|---|
| Anisha Tyagi | Manager, Environmental Health & Safety – Chino Hills |
| Sara Gonzales | Manager, Environmental Health & Safety – North Hollywood/Molecular Genetics Pathology Laboratory (MGPL) |

**Job Classifications with Exposure**

We have determined that some or all of our employees in the following job classifications have occupational exposure when performing certain tasks and procedures:

| **Job classifications where all or some employees have occupational exposure*** |
|---|
| Laboratory Personnel (i.e., Clinical and Pathology) |
| Environmental Services/ Housekeeping |
| Technicians/Technologists (i.e., Biomedical Engineering) |
| Plant Services/Operations (i.e., Facilities/Engineering) |
| Storekeepers (Material Management) |
| Physicians |
| Nurse |

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## Biosafety And Biocontainment Plan, *continued*

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| Safety |
| Clerks |
| Contractors** |
| Trades personnel (*e.g.*, electricians, carpenters, painters, laborers) who may perform work in areas other than high risk departments |

**** There are occasions (e.g., disasters or work stoppages) when healthcare workers may be asked to perform duties involving occupational exposure to blood borne pathogens. In such instances, appropriate actions will be taken to ensure fulfillment of applicable aspects of this exposure control plan.***

**Tasks and Procedures Involving Occupational Exposure**

The following table lists typical tasks that involve potential occupational exposure, including required engineering and work practice controls, and personal protective equipment for each.

High hazard procedures performed at this facility are highlighted in the table (continued on the following pages) and listed below:

| FACILITY | DEPARTMENT(S) | AREA(S) |
|---|---|---|
| 11668 Sherman Way<br>North Hollywood, CA<br>91605 | Bacteriology | TB<br>Mycology |
| | Immunology | PCR room<br>COVID-19 Testing |
| | Virology | PCR Room<br>COVID-19 Testing |
| 13000 Peyton Drive<br>Chino Hills, CA 91605 | Molecular | COVID-19 Testing |
| | Molecular COVID | COVID-19 Testing |

- Additionally, Individuals entering the above areas for look ups, machine repair, cleaning, collecting chemical waste and changing filters.

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## Biosafety And Biocontainment Plan, *continued*

| Tasks and Procedures Involving Occupational Exposure & Exposure Controls | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Legend: R = Routinely necessary; S = If soiling is likely; ** = If splattering is likely, N/P = N95 or PAPR<br>Green highlighted row = aerosol generating procedure | | | | | | | | | | | |
| | | Work Practices | | | | Personal Protective Equipment | | | | | |
| Task/Procedure Involving Occupational Exposure | Use of Engineering Controls (e.g., sharps safety devices) | Universal / Standard Precautions | Hand Washing (e.g., following removal of PPE) | Cleaning Work Are (e.g., wiping up blood and OPIM) | Safe Sharps Work Practices (e.g., proper handling/ disposal) | Follow Protocol to Minimize Splash | Use of Gloves | Use of Gown / Plastic Apron | Use of Mask (fluid protective barrier) | Use of Eye Protection | Use of Respirator (N) N95/(P) PAPR if performed on an unmasked suspected or confirmed ATD patient |
| Centrifugation | R | R | R | R | | R | R | | | ** | N/P[1] |
| Cleaning – blood & body fluid (including spills) | R | R | R | R | | R | R | S | ** | ** | N |
| Instruments Equipment decontaminating | | R | R | S | | ** | R | S | ** | ** | N |
| Plumbing – working on contaminated plumbing | | R | R | R | | R | R | S | | | N |
| Specimen – collection | R | R | R | R | R | R | R | S | ** | ** | N |
| Specimen – processing and handling | R | R | R | R | R | R | R | S | ** | ** | N |

**List of ATPs-L**

We have determined that ATPs-L are either present or reasonably expected to be present in our laboratory materials. We have established biosafety measures to protect our employees from exposure to these ATPs-L and have listed them in the following table. We will take these measures any time we work with materials containing these ATPs-L.

| ATPs-L Known or Expected to be Present in Laboratory Materials | Biosafety Measures |
|---|---|
| ❑ Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease, e.g. Anthrax/*Bacillus anthracis*<br>❑ Avian influenza/Avian influenza A viruses (strains capable of causing serious disease in humans) | The Lab Care Delivery Systems follow universal precautions when handling clinical specimens, all of which may contain potentially infectious materials. Site and activity specific biosafety risk assessment are performed to determine if additional biosafety precautions (such as the need for respiratory protection) are warranted in handling and processing |

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## Biosafety And Biocontainment Plan, *continued*

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| ❑ Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out<br>❑ Measles (rubella)/Measles virus<br>❑ Monkey pox/Monkey pox virus<br>❑ Novel or unknown pathogens<br>❑ Severe acute respiratory syndrome (SARS)<br>❑ Smallpox (variola)/Variola virus<br>❑ Tuberculosis (TB)/*Mycobacterium tuberculosis* -- Extra pulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected<br>❑ Any other disease for which public health guidelines recommend airborne infection isolation<br>❑ Diphtheria pharyngeal<br>❑ Epiglottitis, due to *Haemophilus influenza* type b<br>❑ *Haemophilus influenza* Serotype b (Hib) disease/*Haemophilus influenza* serotype b -- Infants and children<br>❑ Influenza, human (typical seasonal variations)/influenza viruses<br>❑ Meningitis<br>❑ *Haemophilus influenza*, type b known or suspected<br>❑ *Neisseria meningitidis* (meningococcal) known or suspected | specimens that are suspected or confirmed for high risk pathogens (i.e. Francisella, tularensis, Ebola, avian influenza, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community, in adherence to the following regulations, including OSHA's Bloodborne Pathogens (29 CFR 1910.1030), Personal Protective Equipment (29 CFR 1910.132), Respiratory Protection (29 CFR 1910.134), and Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) standards. Routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste are followed in accordance with regulatory standards. |

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## Biosafety And Biocontainment Plan, *continued*

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| ❑ Meningococcal disease sepsis, pneumonia (see also meningitis)<br>❑ Mumps (infectious parotitis) / Mumps virus<br>❑ Mycoplasmal pneumonia<br>❑ Parvovirus B19 infection (erythema infectiosum)<br>❑ Pertussis (whooping cough)<br>❑ Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,<br>❑ Pneumonia<br>❑ Adenovirus<br>❑ Haemophilus influenza Serotype b, infants and children<br>❑ Meningococcal<br>❑ *Mycoplasma, primary atypical*<br>❑ *Streptococcus Group A*<br>❑ Pneumonic plague/*Yersinia pestis*<br>❑ Rubella virus infection (German measles)/Rubella virus<br>❑ Severe acute respiratory syndrome (SARS)<br>❑ Streptococcal disease (group A streptococcus)<br>❑ Skin, wound or burn, Major<br>❑ Pharyngitis in infants and young children<br>❑ Scarlet fever in infants and young children<br>❑ Serious invasive disease<br>❑ Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses (airborne infection isolation and respirator | | |

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## Biosafety And Biocontainment Plan, *continued*

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| use may be required for aerosol-generating procedures)<br>❑ Any other disease for which public health guidelines recommend droplet precautions | |

**Incoming Materials Containing ATPs-L**

It is our policy to treat all incoming materials containing ATPs-L as containing the virulent or wild-type pathogen until we conduct procedures at our laboratory to verify that the pathogen has been deactivated or attenuated.

**Engineering Controls**

For any health or safety hazard, engineering controls are always an important method of mitigating the hazard. In our facility, we use the following engineering controls to minimize exposure to infectious or potentially infectious laboratory aerosols:

| Engineering Control | Procedures for use of the Engineering Control |
|---|---|
| Chemical Fume Hood | Utilized for reducing chemical exposure to personnel when hazardous chemicals, gases or drugs are involved. Chemical Fume Hoods offer **no** product protection, but rather personnel protection only, therefore is **not** considered a "clean environment". Airflow draws inward and is 100% exhausted to the outside by hard duct to the exterior environment. |
| Laminar Flow Hood | Primarily used for research that involves absolutely **no** hazardous material. The units provide **no personnel** protection, but rather product protection only. The term "Clean Bench" is often used to describe the horizontal (direction of airflow) HEPA filtered laminar flow environment. |
| Workstation Hoods or Canopy Hoods | To reduce chemical exposure similar to Chemical Fume Hoods, however the inward draw of air is considerably less than that of a Chemical Fume hood and is only meant to reduce the nuisance levels of less harmful chemicals in use. Some are 100% exhausted outside, while others |

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## Biosafety And Biocontainment Plan, *continued*

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| | utilize a charcoal filter to absorb vapors and exhaust back into the lab environment. These filters must be changed regularly (in accordance with manufacturers recommendations) to avoid saturation. |
| Biological Safety Cabinets | • Keep the unit running at all times. If shut down is necessary, turn on the unit and let run for 5 minutes before use.<br>• Before use, ensure that the airflow is directed into the cabinet and that the exhaust fan is operational (visual airflow indicator is showing inward airflow).<br>• Perform all procedures at least 4" inside the cabinet from the sash.<br>• Ensure the sash is at proper height.<br>• Thoroughly disinfect the work surface after use. |
| Negative Pressure Laboratories | This is standard for all work areas within this laboratory. Air exchanges within all areas where biohazardous materials are present, and work is performed average approximately 15 exchanges per hour. In High-Risk work areas, where aerosolization is possible, the air exchanges are approximately 21-24 per hour. Each area is kept at a slightly negative (10-15%) environment to the outside corridors or hallways. |

**Safe Handling Procedures and Prohibited Practices**

Another level of protection for our employees is mandatory work practices for safely handling materials that contain ATPs-L. Employees must observe the following procedures when handling such materials:

The Lab Care Delivery System follow universal precautions when handling clinical specimens, all of which may contain potentially infectious materials. Site and activity specific biosafety risk assessment are performed to determine if additional biosafety precautions (such as the

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## Biosafety And Biocontainment Plan, *continued*

need for respiratory protection) are warranted in handling and processing specimens that are suspected or confirmed for high risk pathogens (i.e. Francisella, tularensis, Ebola, avian influenza, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community, in adherence to the following regulations, including OSHA's Bloodborne Pathogens (29 CFR 1910.1030), Personal Protective Equipment (29 CFR 1910.132), Respiratory Protection (29 CFR 1910.134), and Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) standards. Routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste are followed in accordance with regulatory standards.

**Centrifuges, Incubators and Autoclaves**

**Centrifuges, Incubators and Autoclaves**

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| **Centrifuges** | Centrifugation can create aerosols. Within the Microbiology section, all swinging-bucket centrifuge rotors shall have bucket covers with safety seals. All fixed-angle centrifuge rotors shall have rotor covers with seals, as well. Opening of the seal must be performed within the BSC. |
| **Incubators** | Incubators do not usually generate aerosols but may accumulate residues that contain bacteria. Cleaning / disinfection of incubators shall be schedule as a regular routine. |
| **Autoclaves** | Autoclaving is a decontamination process for biohazardous material. It is required for all select agents destructed by steam sterilization process and disposed as infectious waste from bacteriology section as indicated in the CDC / NIH BMBL. After autoclave processing, all disposal waste shall be placed into "Red bags" /barrels and disposed of as regular biohazard waste through Stericycle. |

**Labeling Equipment Sent Out for Repair, Surplus, or Disposal**

All equipment that is potentially contaminated by biohazardous material during use must be "tagged" before repairs or disposal, if it cannot be thoroughly decontaminated prior to the work. The Lab Care Delivery Systems uses a "red" / "green" tagging system to indicate the status of decontamination. Check with the Laboratory Technology Services department for acquisition of these tags and procedures to be followed.

**Transport and Shipping**

Any department wishing to ship biological specimens shall have an individual who has been properly trained in the approved DOT/ IATA Shipping Training (see KP Learn courses, general & specific). This trained individual shall be

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## Biosafety And Biocontainment Plan, *continued*

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| **Biological materials** | responsible for package preparation and shipment of biological specimens. Any department wishing to import biological samples may have to complete an additional CDC Importation Permit Application. Please contact the EH&S department for information and/or assistance in completing these importation permits. |
| **Internally Controlled Transport of Biological Materials within Kaiser** | Biological specimens transported between laboratories should be properly contained in a sealed, leak-proof, shatter-proof secondary container. This container should be sealed in the laboratory and the outside should be disinfected. This will allow for safe transport of the specimens by internal couriers. Ensure that labeling is evident on the shipping container and that all information is correct, in case of emergencies. Additional information on packaging & transport may be found in the federal DOT regulations, or by contacting the EH&S department.<br><br>The following activities may increase employee exposure to infectious or potentially infectious laboratory aerosols and are, therefore, prohibited in our laboratory when handling materials that contain ATPs-L (*e.g., sniffing* in vitro *cultures, eating or smoking in the lab, mouth pipetting*):<br><br>Mouth pipetting / suctioning of blood or other potentially infectious materials is prohibited.<br><br>Eating, drinking, smoking, vaping, gum chewing, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure. |
| **Biosafety Guidelines for Specimen Handling and Processing** | The Lab Care Delivery System follow universal precautions when handling clinical specimens, all of which may contain potentially infectious materials. Site and activity specific biosafety risk assessment are performed to determine if additional biosafety precautions (such as the need for respiratory protection) are warranted in handling and processing specimens that are suspected or confirmed for high risk pathogens (i.e. Francisella, tularensis, Ebola, avian influenza, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community, in adherence to the following regulations, including OSHA's Bloodborne Pathogens (29 CFR 1910.1030), Personal Protective Equipment (29 CFR 1910.132), Respiratory Protection (29 CFR 1910.134), and Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) standards. Routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste are followed in accordance with regulatory standards. |

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## Biosafety And Biocontainment Plan, *continued*

**Decon and Disinfection Procedures**

Employees are also at risk of becoming infected with an ATD when coming into contact with surfaces contaminated with ATPs-L. To reduce this risk, we will decontaminate and disinfect laboratory surfaces and equipment using the following procedures:

Laboratory surfaces should be decontaminated after work with biohazardous materials and at the end of the day. Disinfectants should be examined for efficacy against the infectious agent in use. Disinfectants should be prepared according to the manufacturer directions for dilution and shelf-life. Storage of disinfectants should be in properly labeled containers. Information regarding specific disinfectants is available by contacting the EH&S Office.

Testing departments have their own decontamination and disinfection procedures. Please reference MasterControl RRL-PPP-0867.

SCPMG RRL uses the following EPA-registered cleaner(s) or disinfectant(s): household bleach, quaternary ammonium compounds, phenolic compounds, and iodophors.

Decontamination and disinfection will occur according to the following schedule (*e.g., nightly; after every procedure*): before and after use of biological safety cabinet, and before and after every procedure.

The following employees will perform the decontamination and disinfection: Lab Assistant I/II, Clinical Lab Scientist, Lab Technicians, and other personnel that will work in biosafety cabinet or bench.

**Personal Protective Equipment**

In our laboratory, we require specific personal protective equipment (PPE) to be used when conducting certain procedures with ATPs-L to minimize exposure to infectious or potentially infectious aerosols. To assist us in determining the appropriate PPE, we referred to the BMBL, which identifies the minimum required PPE that must be used in biosafety level 3 laboratories.

Lab coats and gloves will be removed prior to leaving the lab. Body protection is required because many pathogens transmit from being carried on clothing. Eye and face protection are required because many pathogens transmit through contact with eyes and mucous membranes.

We describe our PPE requirements in the following table:

| Required PPE Category | PPE Used | Procedures for which the PPE is to be Used |
|---|---|---|
| **Body protection** | **Gowns, Lab Coats, Aprons, and Other** | Gowns, lab coats, aprons, and scrubs protect the wearer's clothing and skin from contamination. As with all PPE, the type of |

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## Biosafety And Biocontainment Plan, *continued*

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| | **Protective Equipment** | clothing needed depends on the task being performed and the degree of exposure anticipated. Solid front wrap-around clothing offers better protection than pull-over type clothing or clothing with front closures. Long sleeved garments with snug fitting cuffs are preferred over open or short sleeves. Snug fitting cuffs prevent splashes, splatters and aerosols from making contact with exposed skin on the lower arms.<br>Longer single-use gloves can be pulled over snug fitting cuffs to seal out any infectious materials.<br>Aprons are necessary for protection against liquids spilling or splashing on clothing. It is recommended that appropriate aprons be worn to protect against the potential harmful effects of liquid waste, especially where there is a high propensity for splashes. |
| **Hand protection** | **Gloves** | Gloves should be comfortable and of sufficient length to prevent exposure of the wrist and forearm. Depending upon intended use, the composition and design of the glove may vary to provide the desired level of flexibility, strength, impermeability, and resistance to penetration by sharp objects, as well as protection against heat and cold. No one glove can be expected to be satisfactory for all intended uses. For the most part, Nitrile gloves offer the most protection for work with chemicals and biological material.<br><br>Disposable (single use) gloves provide a barrier between infectious agents and the skin. Glove use is a basic precept of preventing infectious agent transmission. Breaks in the skin barrier of the hand (damaged cuticles, scrapes, micro-cuts, dermatitis, etc.) are common and the use of hand-lotions is recommended to prevent this.<br>Gloves should be removed, and hands washed before exiting the laboratory and whenever the gloves are grossly |

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## Biosafety And Biocontainment Plan, *continued*

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| | | contaminated or obviously degraded. Use the one glove method or an appropriate secondary container when transporting materials through common use areas. |
| **Eye/face protection** | Face shields, head covers/hoods, protective goggles | Protection of the face and eyes is of prime importance in laboratories due to the potential for foreign material, both liquid and solid, to splash on the head, face and eyes, or contact lenses. The selection is dependent upon materials of construction, fit, comfort, and compatibility with the work and the overall facial area requiring protection. Face shields and goggles worn together can provide the best splash protection. Safety glasses provide impact protection from projectiles in the laboratory, but do not provide adequate splash protection.<br><br>Contact lenses do not provide eye protection. It is recommended that contact lenses not be worn when working around chemicals, fumes, and other hazardous material and dust particles since these items may become trapped in the space between the contact lens and the cornea. When contact lenses are worn, eye protection, such as tight-fitting goggles, shall be worn. Contact lenses should never be handled in the laboratory. |

☐ Other procedures for using the PPE:

| **General Guidelines for the Use of Gloves in the Laboratory:** |
|---|
| Change gloves periodically, when gloves become soiled, and always wash hands after removing gloves or other PPE. |
| Gloves will not prevent needle sticks or other puncture injuries. |
| Check gloves for visible tears before use. |
| **Do not reuse disposable nitrile gloves.** |
| Discard contaminated gloves in a biohazard bag immediately after use. |
| Double glove when cleaning spills. |

- **Best Procedure for Removing PPE**

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## Biosafety And Biocontainment Plan, *continued*

- When removing gloves, grip the outside of one glove at wrist with the other gloved hand, pull glove off inside-out and gather in palm of gloved hand. Place index or middle finger of the ungloved hand on wrist of gloved hand, slide finger under the glove opening and pull glove off inside out.

**Decon and Disinfection Procedures**

Employees are also at risk of becoming infected with an ATD when coming into contact with surfaces contaminated with ATPs-L. To reduce this risk, we will decontaminate and disinfect laboratory surfaces and equipment using the following procedures:

Laboratory surfaces should be decontaminated after work with biohazardous materials and at the end of the day. Disinfectants should be examined for efficacy against the infectious agent in use. Disinfectants should be prepared according to the manufacturer directions for dilution and shelf-life. Storage of disinfectants should be in properly labeled containers. Information regarding specific disinfectants is available by contacting the EH&S Office.

Testing departments have their own decontamination and disinfection procedures. Please reference MasterControl RRL-PPP-0867.

SCPMG RRL uses the following EPA-registered cleaner(s) or disinfectant(s): household bleach, quaternary ammonium compounds, phenolic compounds, and iodophors.

Decontamination and disinfection will occur according to the following schedule (*e.g., nightly; after every procedure*): before and after use of biological safety cabinet, and before and after every procedure.

The following employees will perform the decontamination and disinfection: Lab Assistant I/II, Clinical Lab Scientist, Lab Technicians, and other personnel that will work in biosafety cabinet or bench.

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## Biosafety And Biocontainment Plan, *continued*

**Personal Protective Equipment**

In our laboratory, we require specific personal protective equipment (PPE) to be used when conducting certain procedures with ATPs-L to minimize exposure to infectious or potentially infectious aerosols. To assist us in determining the appropriate PPE, we referred to the BMBL, which identifies the minimum required PPE that must be used in biosafety level 3 laboratories.

Lab coats and gloves will be removed prior to leaving the lab. Body protection is required because many pathogens transmit from being carried on clothing. Eye and face protection are required because many pathogens transmit through contact with eyes and mucous membranes.

We describe our PPE requirements in the following table:

| Required PPE Category | PPE Used | Procedures for Which the PPE Is to Be Used |
|---|---|---|
| **Body protection** | **Gowns, Lab Coats, Aprons, and Other Protective Equipment** | Gowns, lab coats, aprons, and scrubs protect the wearer's clothing and skin from contamination. As with all PPE, the type of clothing needed depends on the task being performed and the degree of exposure anticipated. Solid front wrap-around clothing offers better protection than pull-over type clothing or clothing with front closures. Long sleeved garments with snug fitting cuffs are preferred over open or short sleeves. Snug fitting cuffs prevent splashes, splatters and aerosols from making contact with exposed skin on the lower arms. Longer single-use gloves can be pulled over snug fitting cuffs to seal out any infectious materials. |

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## Biosafety And Biocontainment Plan, *continued*

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| | | Aprons are necessary for protection against liquids spilling or splashing on clothing. It is recommended that appropriate aprons be worn to protect against the potential harmful effects of liquid waste, especially where there is a high propensity for splashes. |
| **Hand protection** | **Gloves** | Gloves should be comfortable and of sufficient length to prevent exposure of the wrist and forearm. Depending upon intended use, the composition and design of the glove may vary to provide the desired level of flexibility, strength, impermeability, and resistance to penetration by sharp objects, as well as protection against heat and cold. No one glove can be expected to be satisfactory for all intended uses. For the most part, Nitrile gloves offer the most protection for work with chemicals and biological material.<br><br>Disposable (single use) gloves provide a barrier between infectious agents and the skin. Glove use is a basic precept of preventing infectious agent transmission. Breaks in the skin barrier of the |

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## Biosafety And Biocontainment Plan, *continued*

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| | | hand (damaged cuticles, scrapes, micro-cuts, dermatitis, etc.) are common and the use of hand-lotions is recommended to prevent this.<br>Gloves should be removed, and hands washed before exiting the laboratory and whenever the gloves are grossly contaminated or obviously degraded. Use the one glove method or an appropriate secondary container when transporting materials through common use areas. |
| **Eye/face protection** | Face shields, head covers/hoods, protective goggles | Protection of the face and eyes is of prime importance in laboratories due to the potential for foreign material, both liquid and solid, to splash on the head, face and eyes, or contact lenses. The selection is dependent upon materials of construction, fit, comfort, and compatibility with the work and the overall facial area requiring protection. Face shields and goggles worn together can provide the best splash protection. Safety glasses provide impact protection from projectiles in the laboratory, but do not |

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## Biosafety And Biocontainment Plan, *continued*

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| | | provide adequate splash protection.<br><br>Contact lenses do not provide eye protection. It is recommended that contact lenses not be worn when working around chemicals, fumes, and other hazardous material and dust particles since these items may become trapped in the space between the contact lens and the cornea. When contact lenses are worn, eye protection, such as tight-fitting goggles, shall be worn. Contact lenses should never be handled in the laboratory. |

☐ Other procedures for using the PPE:

| **General Guidelines for the Use of Gloves in the Laboratory:** |
|---|
| Change gloves periodically, when gloves become soiled, and always wash hands after removing gloves or other PPE. |
| Gloves will not prevent needle sticks or other puncture injuries. |
| Check gloves for visible tears before use. |
| **Do not reuse disposable nitrile gloves.** |
| Discard contaminated gloves in a biohazard bag immediately after use. |
| Double glove when cleaning spills. |

| **Best Procedure for Removing PPE** |
|---|
| When removing gloves, grip the outside of one glove at wrist with the other gloved hand, pull glove off inside-out and gather in palm of gloved hand. Place index or middle finger of the ungloved hand on wrist of gloved hand, slide finger under the glove opening and pull glove off inside out. |
| When removing PPE, remove lab coat or solid front gown first, then remove gloves (aseptically), remove face protection last to avoid touching your face with contaminated hands. If wearing double gloves, remove outer gloves before removing lab coat or solid front gown. |

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## Biosafety And Biocontainment Plan, *continued*

**Respiratory Protection Requirement**

We have conducted a risk assessment and determined that during some operations or under certain conditions, our employees must wear respiratory protection, as described in the following table:

| **Condition or Operation Requiring Respiratory Protection** | **Type of Respiratory Protection Required (*e.g., N95, PAPR, supplied-air*)** |
|---|---|
| Airborne Pathogens (such as tuberculosis and SARs) | • An N95 category or (above) tight–fitting respirator, or<br>• Loose-fitting Powered Air Purifying Respirators (PAPR) with HEPA filters when performing high hazard procedures on suspected or confirmed airborne infectious disease patients<br>*See site Aerosol Transmissible Diseases (ATD) Exposure Control Plan for specific respirator selection requirements for protection from airborne infectious diseases.* |
| Dust, Mist and Particulates | • An air purifying respirator equipped with a NIOSH certified filter for particulates, or<br>• An atmosphere-supplying respirator. |
| Hazardous Gas and Vapor Atmosphere | • An air-purifying respirator that is equipped with either an end of service life indicator or a schedule to change canisters and cartridges based on objective information/data that will ensure that the canisters and cartridges are changed before the end of their service life. The frequency of the respirator use, type and |

*Continued on next page*

## Biosafety And Biocontainment Plan, *continued*

| | |
|---|---|
| | concentration of the contaminants, type of operations, etc., will determine appropriate change-out schedule, or<br><br>An atmosphere-supplying respirator. |
| Immediately Dangerous to Life and Health (IDLH) | • A combination full-face piece supplied-air respirator with auxiliary self-contained air supply.<br>• A full-face piece self-contained breathing apparatus for a minimum service life of thirty minutes<br><br>**Note: Air purifying respirators shall NOT be used in an IDLH situation.** |

Employees who are required to wear respirators will be covered under our written Respiratory Protection Program, in accordance with title 8 sections 5199 and 5144. We provide our employees with medical evaluations to determine whether they are medically fit to wear a respirator, fit tests to ensure that the chosen respirators provide a good seal, and training to ensure that employees understand how to properly use and care for their respirators. See our Respiratory Protection Program for details.

**Emergency Procedures for Uncontrolled or Untreated Releases**

We provide training to and communicate with our employees to minimize the occurrence of accidents. However, sometimes uncontrolled or untreated releases, such as spills of cultures, may still occur inside or outside our laboratory facility.

We have established these emergency procedures for uncontrolled releases inside the laboratory facility:

| **Emergency Procedures for Uncontrolled Releases Inside the Laboratory Facility** |
|---|
| The first essential practice is to avoid inhaling any airborne material by holding the breath and leaving the laboratory. |
| Warn others in the area and go directly to a wash area. |

*Continued on next page*

## Biosafety And Biocontainment Plan, *continued*

| |
|---|
| If clothing is known or suspected to be contaminated, remove the clothing with care, folding the contaminated area inward. |
| Discard the clothing into a bag. Wash all potentially contaminated areas as well as the arms, face, and hands. |
| Shower if facilities are available. |
| Reentry into the laboratory should be delayed for a period of 60 minutes to allow reduction of the aerosol generated by the spill. |
| Advance preparation for management of a spill is essential. |
| If the emergency involves personal injury, call 911. |
| Be sure to state the type of contaminant (biological or chemical); do not state the name of the agent) on the victim. |
| The caller should remain available to brief emergency responders on the type of contamination and proper procedures for handling the material. |
| Block off the spill area and alert personnel in the area to presence of the spill. |
| Vacate area and allow 60 minutes for aerosols to settle. |
| Contact your supervisor and inform them of the situation. |
| Supervisor to notify EH&S/EHS Department. |
| Do not re-enter the area, but rather wait for laboratory response staff. |

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## Biosafety And Biocontainment Plan, *continued*

**Spill of Human Blood, Body Fluids, or Biological Materials**

**Spill of Human Blood, Body Fluids, or Biological Materials**

| General Cleanup Method: |
|---|
| Block off the spill area and alert personnel in the area to the presence of the spill. |
| Put on appropriate PPE. This may include gloves, gown, eye protection, face mask, or respirator depending on the size of the spill and the type of material. |
| Cover the spill with paper towels or other absorbent materials to contain spill. |
| Carefully pour a freshly prepared 1:10 dilution of household bleach or other effective disinfectant around the edges of the spill and into the spill. Avoid splashing. |
| Allow 15-minute contact period or follow Manufacturer's disinfecting wait period. |
| Pick-up all absorbent material and place carefully in a biohazard bag for autoclaving and subsequent disposal. |
| Use forceps, plastic scoop, or other mechanical means to remove any broken glass or other sharp objects from the spill area. Take care not to create aerosols. Place these items into a small cardboard box, plastic bag, or other container that will prevent them from puncturing the biohazard bag (or your hand). Place the enclosed sharp items into the biohazard "red" bag for disposal. |
| Clean spill area with fresh paper towels soaked in disinfectant. Place used paper towels in biohazard bag for disposal. |
| Once spill is completely cleaned, place all used spill control equipment in biohazard bag for disposal. |
| Remove PPE and place in biohazard bag for disposal. |
| Do not remove PPE from face with soiled gloves. Remove soiled gloves first and place them in the biohazard bag for disposal. |
| Wash your hands with soap and water thoroughly. |

**Spill in a Biological Safety Cabinet**

**Spill in a Biological Safety Cabinet**

A spill that is confined to the interior of the biological safety cabinet should present little or no hazard to personnel in the area. However, chemical disinfection procedures should be initiated at once while the cabinet ventilation system continues to operate to prevent escape of contaminants from the cabinet.

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## Biosafety And Biocontainment Plan, *continued*

| Spill in a Biological Safety Cabinet |
|---|
| Wipe walls, work surfaces, and equipment with a disinfectant. |
| Use appropriate approved commercially available chemical germicides known to be effective against the organism in use or 1-part household bleach (e.g. Clorox) to 9 parts of water, prepared fresh daily. |
| The operator should wear gloves and eye protection during this procedure. |
| Use sufficient disinfectant solution to ensure that the drain pans and catch basins below the work surface contain the disinfectant. |
| Lift the front exhaust grill and tray and wipe all surfaces. |
| Wipe the catch basin and drain the disinfectant into a container. |
| This disinfectant, gloves, wiping cloth, and sponges should be discarded as "red" bag waste. |

Note: This procedure will not disinfect the filters, blower, air ducts or other interior parts of the cabinet. Decontamination of these parts shall be performed by CEPA and the biosafety cabinet will have to be re-certified. Contact the EH&S department to determine if decontamination by a contractor is necessary.

**Catastrophic Spill**

**Catastrophic Spill**

If a spill occurs of a known Biosafety Level 2 organism containing material in the laboratory, the first essential practice is to avoid inhaling any airborne material by holding the breath and leaving the laboratory.

| Catastrophic Spill |
|---|
| Warn others in the area and go directly to a wash area. |
| If clothing is known or suspected to be contaminated, remove the clothing with care, folding the contaminated area inward. |
| Discard the clothing into a bag. Wash all potentially contaminated areas as well as the arms, face, and hands. Shower if facilities are available. Reentry into the laboratory should be delayed for a period of at least 30 minutes to allow reduction of the aerosol generated by the spill. Advance preparation for management of a spill is essential. If the emergency involves personal injury, call 911. Be sure to state the type of contaminant (biological or chemical); do not state the name of the agent) on the victim. The caller should remain |

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## Biosafety And Biocontainment Plan, *continued*

| |
|---|
| available to brief emergency responders on the type of contamination and proper procedures for handling the material. |
| Block off the spill area and alert personnel in the area to presence of the spill. |
| Vacate area and allow at least 30 minutes for aerosols to settle. |
| Contact your supervisor and inform them of the situation. |
| Do not re-enter the area, but rather wait for laboratory response staff. |

Note: Emergency Responders must don specific appropriate protective equipment.

**Personal Contamination**

**Personal Contamination**

Remove any contaminated clothing or PPE.

- If skin has been contaminated, wash with soap and warm water.
- If eyes have been splashed, rinse under tepid running water (eyewash or faucet) for at least 15 minutes.
- Contact your Supervisor or Manager and inform them of the situation.
- Follow procedures to seek medical attention if needed.

Note: Emergency Responders must don specific appropriate protective equipment.

All personnel should be familiar with the location and use of all the emergency equipment in their laboratory. This includes fire extinguishers, eyewash stations, emergency deluge showers, chemical spill kits, absorbent materials, and fire alarm pull stations. For certain areas, respiratory protection may be required for routine and emergency operations. If respirators are required, the laboratory has a written Respiratory Protection Program and all users shall be fit-tested and trained in their use on an annual basis.

The following supplies and equipment will also be used in emergency response involving ATPs-L: Powered Air-Purifying Respirator (PAPR). We will also report such incidents to the local health officer using the following procedures:

- For select agent reporting if an exposure occurred with select agent CDC Form 3 is completed and reported to CDC Select Agents Compliance Officer by Bacteriology Managers and Assistant Directors. Refer to Master Control RRL-BAC-0246.

Contact information for the local health officer: RRL Employee Health Services will contact local health officer

- North Hollywood/Electronics Place: (818) 503-6803
- Chino Hills: (909) 902-2808

**Medical Services**

Due to our employees' exposure to ATPs-L, we provide medical services to prevent them from becoming infected and also to provide medical care after exposure incidents. These are provided at no cost to our employees.

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## Biosafety And Biocontainment Plan, *continued*

**Vaccinations**

Vaccinations are a safe and effective way to prevent the spread of vaccine-preventable diseases. Therefore, we offer our employees all appropriate vaccinations in accordance with the BMBL for the specific laboratory operations performed at our facility.

We make the following vaccinations available to our employees, based on the aerosol transmissible pathogens-laboratory they work with that are capable of becoming aerosolized through our laboratory procedures:

a. For ATD prevention, provide to all susceptible health care workers with occupational exposure all vaccine doses listed as recommended in Cal/OSHA ATD Standard's 8 CCR 5199 Appendix D. See pertinent Employee Health Guidelines: This includes but not limited to MMRV for all health care workers based on the laboratory baseline and Meningococcal vaccinations for Bacteriology health care workers with potential for exposure. Employees in laboratory operations outside of health care settings, and within the scope of subsection (f), shall be provided with vaccines in accordance with the BMBL for the specific laboratory operations. The requirements in subsection (h)(5) became effective on September 1, 2010.

We send our employees to the following medical provider for vaccinations: Employee Health Services and/or nearby Kaiser Permanente Medical Office facility.

We will offer the vaccinations to occupationally exposed employees after providing the required training (*see the "Training" section of this program below*) within 10 working days of initial assignment to duties where they have occupational exposure.

We will offer the vaccination unless any of the following three conditions exists:

1. The employee has previously received the recommended vaccination and is not due to receive it again.
2. A PLHCP has determined that the employee is immune in accordance with applicable public health guidelines.
3. The vaccine is contraindicated for medical reasons.

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## Biosafety And Biocontainment Plan, *continued*

We will make additional vaccine doses available to employees within 120 days of the issuance of any new applicable public health guidelines recommending the additional dose.

We do not require our employees to participate in a prescreening serology program prior to receiving a vaccine, unless applicable public health guidelines recommend this prescreening prior to administration of the vaccine.

We train our employees on the benefits of receiving vaccinations and strongly encourage them to get vaccinated. However, employees have the option to decline receiving any of the recommended vaccinations. If an employee declines a vaccination, they must sign the appropriate declination form. This form will be kept in their employee file.

If an employee declines any vaccination, we will have them sign a declination containing the following wording, completed with the name of appropriate disease or pathogen.

**Vaccination Declination Statement**

| **Vaccination Declination Statement** |
|---|
| I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with (*name of disease or pathogen*). I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring *(name of disease)*, a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.<br><br>(*End of declination statement*.) |

If the employee initially declines a vaccination but at a later date, while still covered under the standard, decides to accept the vaccination, we will make the vaccination available within 10 working days of receiving a written request from the employee.

☒ (*check if applicable*) Our employees work with strains of seasonal influenza. If the available influenza vaccination covers the particular strain of influenza, then

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## Biosafety And Biocontainment Plan, *continued*

we will provide the vaccine to those employees who have occupational exposure. The vaccination is provided at no cost to them during the period designated by the CDC (*flu season*), which generally begins in October and can last through as late as May.

We send our employees to: Employee Health Services to receive the seasonal influenza vaccine.

We also train our employees on the benefits of receiving the influenza vaccine and strongly encourage them to receive it. However, employees have the option to decline the vaccination. If an employee declines the seasonal influenza vaccination, we will have the employee sign the following declination and keep it in their employee file. This will be done each flu season as long as the employee has occupational exposure.

**Seasonal Influenza Vaccination Declination Statement**

| **Seasonal Influenza Vaccination Declination Statement** |
|---|
| I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring seasonal influenza. I have been given the opportunity to be vaccinated against this infection at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at increased risk of acquiring influenza. If, during the season for which the CDC recommends administration of the influenza vaccine, I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.<br><br>(End of declination statement.) |

If the employee later decides to accept the influenza vaccination and the vaccine is still available, then we will provide it to the employee within 10 days of receiving a written request from the employee.

If any applicable vaccine is not available due to shortages or other reasons, we will document our efforts made to obtain the vaccine in a timely manner and inform the employees of the status of vaccine availability, including when the vaccine is likely to become available.

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## Biosafety And Biocontainment Plan, *continued*

Our procedure for communicating vaccine availability to our employees in these instances is: Presented in Management Daily Operation Briefing, LMP Council Meetings, Workplace Safety Committee Meetings, and communication through email to all Managers and Directors.

Our procedure for documenting the unavailability of a recommended vaccine is to include the name of the person who determined the vaccine was not available, identity of the person providing the vaccine availability information and the date of contact. This record is kept for 3 years. At this facility, these records are kept by: Employee Health.

**Latent TB Infection Assessment**

*(Check the following box only if you will be providing LTBI assessments to your employees.)*

☒ In our laboratory, employees work with materials containing or reasonably anticipated to contain *Mycobacterium tuberculosis*, so we must offer those employees an annual assessment for latent TB infection (LTBI), which may consist of the TB skin test, TB blood test, or TB screening questionnaire.

If applicable public health guidelines or the local health officer recommends more frequent testing, then we will comply with the recommendation.

We send our employees to the following facility for the LTBI screening: Employee Health Services.

Employees with a baseline positive TB test will receive the annual symptom screen questionnaire. If the questionnaire results indicate further testing is needed, then we offer that employee a follow-up screening (PPD, blood test, or chest x-ray) using the following procedures:

a) Any healthcare employee in a designated high-risk department as identified in the most recent CDC TB Risk Assessment (high risk departments at this facility: Bacteriology) will receive TB screening testing (if previous test negative) or complete a Positive TB Screening Questionnaire every 12 months or more frequently based on Infection Prevention annual risk assessment (see Employee Health Services for current TB Screening Questionnaire).

b) Any healthcare employee not in a designated high-risk department will receive TB screening testing (if previous test negative) or will complete a Positive TB Screening Questionnaire (if previous skin

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## Biosafety And Biocontainment Plan, *continued*

test positive) every 12 months or per state requirements, which will be coordinated by Employee Health Services.

c) If there is a cluster of conversions at any time (more than 2) in one department, screening needs to be repeated in 3 months on all employees in that department at that time.

If employees experience a TB conversion, we will refer them to the following PLHCP knowledgeable about TB for evaluation: Occupational Medicine

In the event of a TB conversion, we will also do the following:

4. Provide the PLHCP with a copy of title 8 CCR 5199 and the employee's TB test records. If we have determined the source of the infection, we will also provide any available diagnostic test results including drug susceptibility patterns relating to the source patient.
5. We will request that the PLHCP, with the employee's consent, perform any necessary diagnostic tests and inform the employee about appropriate treatment options.
6. We will request that the PLHCP determine if the employee is a TB case or suspected case, and to do all of the following, if the employee is a case or suspected case:

   Inform the employee and the local health officer in accordance with title 17.

   Consult with the local health officer and inform us of any infection control recommendations related to the employee's activity in the workplace.

   Make a recommendation to us regarding precautionary removal due to suspect active disease, in accordance with subsection (h)(8) of 8CCR 5199, and provide us a written opinion in accordance with subsection (h)(9).

The person responsible for implementing the above TB screening procedures is: Employee Health Nurse

The person who will receive information from the PLHCP regarding infection control recommendations for and precautionary removal of employees who are TB cases or suspected cases is: Employee Health Nurse This person will also communicate the recommendations to the following managers or staff members, if applicable.

In the event of a TB conversion, we will also record the case on the Cal/OSHA Form 300 Log of Work-Related Injuries and Illnesses by placing a check in the "respiratory condition" column and entering "privacy case" in the space normally

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## Biosafety And Biocontainment Plan, *continued*

used for the employee's name. We will also investigate the circumstances of the conversion and correct any deficiencies in the procedures, engineering controls, or PPE that were involved.

List the job titles and roles of staff involved in investigating the circumstances of the conversion and correcting deficiencies (*e.g., biological safety officer, infection prevention officer, employee health coordinator, safety manager*): Employee Health Nurse

We will also document the investigation using the following procedure: Document a written opinion of the medical evaluation within 15 working days of completion of the evaluation, including employee's test status for the exposure of concern, employee's infectivity status, a statement that the employee has been informed of the results of medical evaluation, treatment options and any recommendations, including work restrictions (precautionary removal) as appropriate.

**Exposure Incidents**

| Term | Definition |
|---|---|
| **Exposure Incident (*laboratory*)** | An "exposure incident (*laboratory*)" is defined as a significant exposure to an aerosol containing an ATP-L, without the benefit of applicable exposure control measures. |
| **Significant Exposure** | A "significant exposure" is an exposure to a source of ATPs-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a physician or other licensed health care provider (PLHCP). |

In the event of an exposure incident (*laboratory*), we will offer medical services to our employees who were exposed to the ATPs-L and conduct an incident investigation using procedures described in this section of this Biosafety Plan.

In order to notify our employees who were exposed to the ATP-L, we will first conduct an analysis of the exposure scenario to determine which of our employees

*Continued on next page*

## Biosafety And Biocontainment Plan, *continued*

had significant exposure. This analysis will be completed within a timeframe reasonable for the specific disease.

The person responsible for conducting this analysis is: Employee Health Nurse

We will document the analysis, recording the names and any other employee identifier used at the workplace of persons who were included in the analysis.
If the analysis determines that either of the following conditions exists for an employee, then that employee does not require post-exposure follow-up, and we will document the basis for the determination:

- The employee did not have significant exposure.
- PLHCP determined that the employee is immune to the infection.

We will also document the name of the person who made the determination and the identity of any PLHCP or local health officer consulted in making the determination
We will make the exposure analysis available to the local health officer upon request.

After determining which of our employees had significant exposure, we will notify them of the date, time, and nature of their exposure within a timeframe reasonable for the specific disease, but no later than 96 hours of becoming aware of the potential exposure.
Our procedures to notify our employees who had significant exposure are as follows: inform employee directly and inform immediate Supervisor/Manager.

As soon as feasible, we will provide all of our employees who had a significant exposure a post-exposure medical evaluation by a PLHCP knowledgeable about the specific disease, including appropriate vaccination, prophylaxis, and treatment. For *M. tuberculosis* (the group of different bacterial species that cause tuberculosis) and for other pathogens where recommended by applicable public health guidelines, this will include testing of the isolate from the source individual or material for drug susceptibility, unless the PLHCP determines that it is not feasible.

Employee Health Nurse will provide the following information to the PLHCP:

7. A description of the exposed employee's duties as they relate to the exposure incident.
8. The circumstances under which the exposure incident occurred.
9. Any available diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure that could assist in the medical management of the employee.

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## Biosafety And Biocontainment Plan, *continued*

10. All of the employer's medical records for the employee that are relevant to the management of the employee, including tuberculin skin test results and other relevant tests for ATP infections, vaccination status, and determinations of immunity.

We will also ensure that any PLHCP responsible for making determinations and performing procedures as part of the medical services program are provided a copy of title 8 CCR 5199, and applicable public health guidelines.

We will request from the evaluating PLHCP an opinion on whether precautionary removal from the employee's regular job assignment is necessary to prevent the employee from spreading the disease agent and what type of alternative work assignment may be provided. We will request that any recommendation for precautionary removal be made immediately by phone or fax and also in writing.

The person responsible for requesting and receiving the PLHCP's written opinion is: Employee Health Nurse

We will obtain and provide the employee a copy of the PLHCP written opinion within 15 working days of completion of all required medical evaluations.
If the PLHCP or local health officer recommends precautionary removal, we will maintain the employee's earnings, seniority, and all other employee rights and benefits until the employee is determined to be noninfectious. This includes the employee's right to return to their former job status, as if they had not been removed or otherwise medically limited.

For TB conversions and all ATP-L exposure incidents, the written opinion will consist of only the following information:

11. The employee's TB test status or applicable RATD test status for the exposure of concern.
12. The employee's infectivity status.
13. A statement that the employee has been informed of the results of the medical evaluation and has been offered any applicable vaccinations, prophylaxis, or treatment.
14. A statement that the employee has been told about any medical conditions resulting from exposure to TB, other RATD or ATP-L, that require further evaluation or treatment and that the employee has been informed of treatment options.
15. Any recommendations for precautionary removal from the employee's regular assignment.

Investigation of exposure incidents (*laboratory*) is necessary to determine what happened, so that we may correct any deficiencies in the procedures, engineering controls, or PPE that were involved to prevent reoccurrence.

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## Biosafety And Biocontainment Plan, *continued*

**Communication of Hazards and Employee Training**

We provide training to our employees who have occupational exposure to ATP-L, as listed at the beginning of this biosafety plan. This training will be provided to each employee in those job categories when they are initially assigned to tasks where they may have occupational exposure and at least annually thereafter, within 12 months of the previous training.

This is how we ensure employees receive their initial training:

At this Facility, EH&S Director and EH&S Managers are responsible for overseeing the ATD training program, including the following elements:

1. Ensure the education is provided by someone knowledgeable in the subject matter covered and is appropriate to educational background, literacy and language background of participants, and that there is time allocated for interactive questions and answers during the training sessions.

2. All employees will receive ATD training during New Employee Orientation (NEO) at Kaiser Permanente, Walnut Center location and annually thereafter not to exceed the 12 months. Additional training will be provided when changes to controls, tasks or procedures affect the employees. Training shall include any changes, modification, or addition to the plan.

3. Training material must be appropriate to the literacy and education level of the employees. ATD training will be completed on KP Learn and is included in the new employee and annual safety curriculum

4. Every training shall include an opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter. Training that is not given in person shall provide answers to questions within 24 hours by a knowledgeable person.

5. At a minimum, the training program shall include:

   i. location of the regulatory text of the ATD Standard and explanation of its contents;

   ii. general explanation of ATDs including signs and symptoms that require medical evaluation;

   iii. modes of disease transmission and the differences between TB infection and disease; applicable source control procedures; consequences and treatment of ATD, including role of incomplete treatment in the development of drug resistant pathogens e.g. MDR TB;

   iv. an explanation of the facility ATD Exposure Control Plan including the Employer and employee's responsibilities in preventing ATD transmission, the Medical Center procedures designed to prevent ATD exposure (e.g. prompt

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## Biosafety And Biocontainment Plan, *continued*

identification, referral and patient isolation), and methods used to communicate to staff the presence of suspected or confirmed ATD cases;

v. how to obtain a copy of the facility's Exposure Control Plan (ECP) and how to provide input;

vi. tasks and activities that may put the employee at risk for ATD;

vii. explanation of engineering and work practice controls, decontamination and disinfection procedures, and use of PPE;

viii. explanation of PPE selection, use and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the PPE required for use;

ix. TB surveillance procedures, requirement and information that immune-compromised persons may have false negative test for latent TB infection;

x. training that meets requirements of the Cal/OSHA Respiratory Protection Standard (8 CCR 5144) for those employees required to use a respirator;

xi. vaccines information including seasonal influenza vaccine and their availability (free of charge);

xii. procedures for reporting exposure incident, medical follow-up and post exposure evaluation; and

xiii. information on the medical center's surge plan and emergency management plan

6. Ensure that documentation of training records for all employees will be kept for a minimum of 3 years and will contain employee name or identifier, dates of training and name of instructor.

The trainings are provided online but we have ensured that all required topics are covered and that interactive questions are answered within 24 hours by a person knowledgeable in the subject matter as it relates to our workplace, and who is also knowledgeable in our Biosafety Plan.
Trainings will include the following topics:

16. An accessible copy of the regulatory text of this standard and an explanation of its contents.
17. A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation.

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## Biosafety And Biocontainment Plan, *continued*

18. An explanation of the modes of transmission of ATPs-L and applicable source control procedures.
19. An explanation of the employer's Biosafety Plan, and the means by which the employee can obtain a copy of the written plan and how they can provide input as to its effectiveness.
20. An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATPs or ATPs-L.
21. An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs or ATPs-L including appropriate engineering and work practice controls, decontamination and disinfection procedures, and personal and respiratory protective equipment.
22. An explanation of the basis for selection of personal protective equipment, its uses and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the items of personal protective equipment employees will use.
23. A description of the employer's TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI.
    ☐ (*check only if applicable*) We are a research or production laboratory and *M. tuberculosis*-containing materials are not reasonably anticipated to be present, so we do not need to include training on surveillance for LTBI.
24. Training meeting the requirements of section 5144(k) of these orders for employees whose assignment includes the use of a respirator.
25. Information on the vaccines made available by the employer, including information on their efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
26. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available, and post-exposure evaluation.
27. Information on the employer's surge plan as it pertains to the duties that employees will perform. As applicable, this training will cover the plan for surge procedures for handling of specimens, including specimens from persons who may have been contaminated as the result of a release of a biological agent, how to access supplies needed for the response including personal protective equipment and respirators, decontamination facilities and procedures, and how to coordinate with emergency response personnel from other agencies.

**Obtaining Active Involvement of Employees in Reviewing and Updating the Biosafety Plan**

As part of our annual review process to update our Biosafety Plan, we obtain the active involvement of employees, not just managers and supervisors.

These are our procedures to obtain the active involvement of employees, with respect to the procedures performed in their respective work areas or departments

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## Biosafety And Biocontainment Plan, *continued*

(*e.g., actively asking employees for input in meetings, soliciting during annual trainings, putting employees on the committee to annually review and update the plan*).

**Review of Plans for Facility Design and Construction**

The designated departments will review the plans for any new facility design and construction prior to the start of the work if it may affect the control measures for ATPs-L. This will allow us to notice any design element that may interfere with our present control measures before it is installed, so we can have it changed before it is too late.

This review will also be done if we move into a new laboratory facility.

**Inspection of Laboratory Facilities**

Regular inspections of our laboratory facilities must be performed so that hazards may be found and corrected in a timely manner. Our inspections include an audit of our biosafety procedures as well as a physical inspection of the facilities and equipment.

We perform these inspections with the following frequency (*at least once per year*): inspections are performed quarterly throughout the year during rounding.

These inspections will be conducted by the EH&S Department and Engineering/Facilities Team.

This group will document the hazards found during the inspections and the corrective action taken for each hazard using the following procedures: communication to corresponding departments through KP Rounding portal.

Hazards will be corrected by following the procedures in our Injury and Illness Prevention Program for hazard correction, including correcting imminent hazards immediately, if possible.

**Controlled Documents**

The following controlled documents support this policy.

| References | |
|---|---|
| Wilson, Deborah E and Chosewood, L. Casey. Biosafety in Microbiological and Biomedical Laboratories (BMBL), Fifth Edition, 2007. | |
| Aerosol Transmissible Diseases Exposure Control Plan | RRL-EHS-0051 |

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## Biosafety And Biocontainment Plan, *continued*

**Author(s)** EH&S Department

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