Aerosol Transmissible Diseases Program

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Table of Contents
1. Purpose ......................................................................................................................... 1
2. Scope ............................................................................................................................ 1
3. Research Laboratory Operations Involving ATPs or Zoonotic ATPs [5199(f)] .................. 2
   3.1. Applications to the Administrative Panel on Biosafety (APB) ................................. 2
   3.2. Implementation ........................................................................................................ 2
   3.3. Written Local Biosafety Plan [5199(f)(4)] .............................................................. 2
   3.4. Training [5199(i)] .................................................................................................. 3
3.5. Inspection of Laboratory Facilities [5199(f)(4)(O)] ...................................................... 4
3.6. Facility Design and Construction [5199(f)(4)(N)] ...................................................... 4
   4.1. Basic Requirements ............................................................................................... 4
   4.2. Laboratory Animal Occupational Health Program .................................................. 5
   4.3. Animal Biosafety Level 3 (ABSL-3) or Above [5199.1(a)(2)(F)] .............................. 5
      4.3.1. Restricted Area [5199.1(d)(2)] ..................................................................... 6
      4.3.2. Personal Protective Equipment (PPE) [5199.1(d)(3)] ........................................ 6
      4.3.3. Respiratory Protection [5199.1(d)(4)] .............................................................. 6
      4.3.4. Application of Toxic or Asphyxiant Gases [5199.1(d)(5)] ............................... 6
      4.3.5. Disposal [5199.1(d)(6)] ................................................................................... 7
      4.3.6. Decontamination [5199.1(d)(7)] ..................................................................... 7
      4.3.7. Medical Services [5199.1(d)(8)] ................................................................. 7
      4.3.8. Training [5199.1(d)(9)] ................................................................................ 8
   4.4. Recordkeeping ........................................................................................................ 8
5. SU Occupational Health Clinic (SUOHC), Department of Public Safety (DPS), and Other Operations as Determined by the Biosafety Officer ........................................................................... 8
   5.1. General .................................................................................................................... 8
   5.2. Program Administrator ........................................................................................ 9
   5.3. Written Infection Control Procedures .................................................................... 9
   5.4. Training [5199(c)(7)] .......................................................................................... 10
   5.5. Annual Review ...................................................................................................... 11
6. Blood Center .................................................................................................................. 11
   6.1. Laboratory [5199(f)] ............................................................................................ 11
Appendix A – Aerosol Transmissible Diseases/Pathogens ................................................................. 20
Appendix B – Aerosol Transmissible Pathogens – Laboratory ......................................................... 22
Appendix C1 – Vaccination Declination Statement ........................................................................ 25
Appendix C2 – Seasonal Influenza Vaccination Declination Statement ........................................ 26
Appendix D – Aerosol Transmissible Disease Vaccination Recommendations for Susceptible Health Care Workers ........................................................................................................ 27
Appendix E – Definitions .................................................................................................................. 28
Appendix F – Resources ................................................................................................................... 36
External Resources .......................................................................................................................... 36
1. Purpose

“Stanford University makes all reasonable efforts to:

- Protect the health and safety of Stanford University faculty, staff, and students.
- Provide safe work practices - academic, research, and administrative - for faculty, staff and students.
- Provide information to faculty, staff, and students about health and safety hazards.
- Identify and correct health and safety hazards and encourage faculty, staff, and students to report hazards.
- Provide information and safeguards for those on campus and in the surrounding community regarding environmental hazards arising from operations at Stanford University.”

To fulfill this University policy and to comply with California Code of Regulations, Title 8, Section 5199, Aerosol Transmissible Diseases (8 CCR 5199) and 8 CCR 5199.1, Aerosol Transmissible Diseases – Zoonotic, this Aerosol Transmissible Diseases Program (hereafter referred to as “ATD Program”) has been developed to minimize personnel exposure to aerosol transmissible diseases (ATDs) in research, healthcare, as well as other settings at Stanford University.

Requirements outlined in this program document are mandatory by the Cal/OSHA Aerosol Transmissible Diseases standard where the word “shall” is used and are advisory in nature where the word “should” is used. Stanford University requirements are noted where the word “must” is used.

2. Scope

This ATD program covers all Stanford University personnel with occupational exposure to aerosol transmissible pathogens (ATPs), aerosol transmissible pathogens-laboratory (ATPs-L), and zoonotic ATPs.

Operations at Stanford University that may have personnel with occupational exposure include:

- Laboratory operations involving ATPs-L, zoonotic ATPs, or samples, cultures, or other materials potentially containing zoonotic aerosol transmissible pathogens (zoonotic ATPs) [5199(a)(1)(G) and 5199.1 (a)(1)(A)]
- Research animal facilities [5199.1 (a)(1)(A)]
- Operations involving wildlife [5199.1 (a)(1)(A)]
- Stanford University Occupational Health Center (SUOHC) [5199(a)(1)(A)(3)]
- Stanford University Department of Public Safety [5199(a)(1)(C)]
  - Police services provided during transport or detention of persons reasonably anticipated to be cases or suspected cases or aerosol transmissible diseases
  - Police services provided in conjunction with health care or public health operations
- Stanford Blood Center [5199(a)(1)(G)]

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2 http://www.dir.ca.gov/Title8/5199.html
3 http://www.dir.ca.gov/Title8/5199-1.html
• Other operations, as needed, that are identified by the Biosafety Officer

3. Research Laboratory Operations Involving ATPs or Zoonotic ATPs [5199(f)]

3.1. Applications to the Administrative Panel on Biosafety (APB)

Labs at Stanford that work with Aerosol Transmissible Pathogens-Laboratory (ATPs-L) or zoonotic ATPs must submit an application to the APB for the possession, storage, transfer, and use of the biohazardous materials. The application must be reviewed and approved by the APB before a lab is permitted to work with ATPs-L or zoonotic ATPs. The APB shall evaluate the engineering controls and PPE requirements during the APB review process.

Approved APB applications shall provide a risk assessment in accordance with the methodology included in Section II of Biosafety in Microbiological and Biomedical Laboratories (BMBL) for each agent and procedure involving the handling of ATPs-L or zoonotic ATPs. The application will contain sufficient information and detail to serve as a useful training document for laboratory employees and students. The application will describe the procedures and measures to establish, implement and maintain an effective program to minimize research laboratory employee exposure to ATPs-L and/or zoonotic ATPs. The application will include a Medical Surveillance Program that ensures all vaccinations, as recommended by applicable public health guidelines, are available for specific laboratory operations, as well as methods for investigation and medical follow up for exposure incidents.

3.2. Implementation

The Principal Investigator/Lab Supervisor is responsible for implementing the procedures and measures described in the approved APB application.

3.3. Written Local Biosafety Plan [5199(f)(4)]

Labs shall establish, implement, and maintain an effective written local Biosafety Plan (BSP) to minimize employee exposure to ATPs-L that may be transmitted by laboratory aerosols. The BSP may be incorporated into an existing local Exposure Control Plan for bloodborne pathogens and shall do all of the following:

• Include a list of all job classifications in which all or some employees have occupational exposure, and a list of all tasks and procedures in which employees have occupational exposure. [5199(f)(4)(B)]
• Include a list of ATPs-L known or reasonably expected to be present in laboratory materials and the applicable biosafety measures. [5199(f)(4)(C)]
• Include a requirement that all incoming materials containing ATPs-L are to be treated as containing the virulent or wild-type pathogen, until procedures have been conducted at the laboratory to verify that a pathogen has been deactivated or attenuated. [5199(f)(4)(D)]
• Identify and describe the use of engineering controls, including containment equipment and procedures, to be used to minimize exposure to infectious or potentially infectious laboratory aerosols. [5199(f)(4)(E)]
• Establish safe handling procedures and prohibit practices, such as sniffing in vitro cultures, that may increase employee exposure to infectious agents.  [5199(f)(4)(F)]
• Establish effective decontamination and disinfection procedures for laboratory surfaces and equipment.  [5199(f)(4)(G)]
• Identify and describe the use of the appropriate personal protective equipment to be used to minimize exposure to infectious or potentially infectious laboratory aerosols.  [5199(f)(4)(H)]
• Identify any operations or conditions in which respiratory protection will be required.
• Establish emergency procedures for uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility.  These procedures shall include effective means of reporting such incidents to the local health officer.  [5199(f)(4)(J)]
• Include procedures for communication of hazards and employee training that complies with Section 3.4 of this program.  This shall include training in the Stanford University ATD Program, the Local Biosafety Plan, and emergency procedures.  [5199(f)(4)(L)]
• Include an effective procedure for obtaining the active involvement of employees in reviewing and updating the Local Biosafety Plan with respect to the procedures performed by employees in their respective work areas or departments on an annual (or more frequent) basis.  [5199(f)(4)(M)]
• Include procedures for inspection of laboratory facilities, including an audit of biosafety procedures.  These inspections shall be performed at least annually.  Hazards found during the inspection, and actions taken to correct hazards, shall be recorded.  [5199(f)(4)(O)]

3.4. Training [5199(i)]

Training shall be provided to all employees with occupational exposure as follows:  [5199(i)(2)]

• At the time of initial assignment to tasks where occupational exposure may take place.
• At least annually thereafter, not to exceed 12 months from the previous training.
• When changes, such as introduction of new engineering or work practice controls, modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure or control measures.  The additional training may be limited to addressing the new exposures or control measures.

Training shall include the following elements:  [5199(i)(4)]

• An accessible copy of the regulatory text of 8CCR 5199 and an explanation of its contents.  [5199(i)(4)(A)]
• A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation.  [5199(i)(4)(B)]
• An explanation of the modes of transmission ATPs-L.  [5199(i)(4)(C)]
• An explanation of the Stanford University ATD Program and the local Biosafety Plan, and the means by which the employee can obtain a copy of these written plans and how they can provide input as to its effectiveness.  [5199(i)(4)(D)]
• An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATPs-L.  [5199(i)(4)(E)]
• An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs-L including appropriate engineering and work practice controls, decontamination
and disinfection procedures, and personal and respiratory protective equipment. [5199(i)(4)(F)]

- 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. [5199(i)(4)(G)]

- A description of the University’s TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for latent TB infection (LTBI). EXCEPTION: Laboratories do not need to include training on surveillance for LTBI if M. tuberculosis containing materials are not reasonable anticipated to be present in the laboratory. [5199(i)(4)(H)]

- 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. [5199(i)(4)(J)]

- 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. [5199(i)(4)(K)]

The training program shall include an opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter of the training as it relates to the workplace that the training addresses and who is also knowledgeable in the Stanford University ATD Program and the local biosafety plan.

3.5. Inspection of Laboratory Facilities [5199(f)(4)(O)]

An inspection of laboratory facilities, including an audit of biosafety procedures, shall be conducted at least annually.

3.6. Facility Design and Construction [5199(f)(4)(N)]

The Biosafety Officer shall review plans for facility design and construction that will affect the control measures for ATPs-L.


This section applies to operations involving vertebrate research animals and wildlife operations.

Examples of wildlife operations at Stanford include:
- Capture, sampling, transportation or disposal of wild birds or other wildlife for research purposes.
- Disposal of wildlife remains or waste by employees.

4.1. Basic Requirements

As part of the Stanford University Injury and Illness Prevention Program (IIPP), all operations involving research animals or wildlife shall establish, implement, and maintain effective procedures.
for preventing employee exposure to zoonotic aerosol transmissible pathogens. These procedures shall include sanitation, investigation of occupational injuries and illnesses, training, and where applicable, biosecurity and the use of PPE. Training shall cover all of the exposure control procedures. [5199.1(a)(2)(A)]

In addition to the above requirements, vertebrate animal research facilities shall perform and document a risk assessment and adopt control measures consistent with the BMBL. [5199.1(a)(2)(F)]

4.2. Laboratory Animal Occupational Health Program

University policy requires that all faculty, staff, visiting scholars, and students who work directly with vertebrate animals, unfixed animal tissues or body fluids, and those who work in animal housing areas must participate in the Laboratory Animal Occupational Health Program (LAOHP). Information on the LAOHP is available at http://www.stanford.edu/dept/EHS/prod/researchlab/medsurv/labanimal/index.html

4.3. Animal Biosafety Level 3 (ABSL-3) or Above and Wildlife Operations Involving Potentially Infected Animals [5199.1(a)(2)(F), 5199.1(a)(2)(D)]

Prior to operations where ABSL-3 or above practices are required and prior to wildlife operations involving handling or disposing of animals likely to be infected with zoonotic ATPs, local ATD plans shall establish, implement, and maintain written zoonotic disease control procedures to control the risk of transmission of disease. These procedures shall be onsite at all times. [5199.1(d)]

These procedures shall include the following: [5199.1(d)(1)]

- A detailed work plan including an assessment of the risks to employees, including biological, chemical, physical, and safety hazards, and a description of site control measures including designating a restricted area consisting of contaminated zones and contaminant reduction zones. Support equipment and personnel shall be staged outside the restricted area.
- A list of all jobs, tasks, or procedures in which employees may have occupational exposure.
- The measures used to control personnel exposure, including each of the following:
  - Engineering controls, work practice controls, and exposure monitoring
  - Procedures for the safe handling of hazardous substances, including hazardous substances used for disinfection and decontamination
  - Procedures for the application of toxic or asphyxiating gases, if such gases are to be used in the operation
  - Respiratory protection
  - Personal protective equipment and protective clothing
  - Decontamination procedures
  - Disposal of animal waste and contaminated personal protective equipment
  - Medical services
  - Training
  - Recordkeeping

4 Consult with the Biosafety Officer, as needed, to determine the likelihood of wildlife being infected with ATPs-Zoonotic.
Procedures to provide employees ready or frequent access to drinking water and sanitation facilities, including appropriate decontamination methods for employees who need to access these facilities.

Procedures to protect employees from the risk of heat illness.

4.3.1. Restricted Area [5199.1(d)(2)]

Operations in the restricted area shall be supervised at all times by a person knowledgeable about and authorized by research animal facilities to enforce the zoonotic disease control procedures.

The supervisor shall ensure that all persons entering the restricted area have been trained in the control procedures applicable to the site or operation and are protected as required by the procedures.

The supervisor shall record the identity and time of entry and exit for each person who enters and/or exits the restricted area.

4.3.2. Personal Protective Equipment (PPE) [5199.1(d)(3)]

Research animal facilities shall conduct a PPE hazard assessment, and provide and ensure the use of PPE consistent with BMBL [5199.1(2)(F)] and Stanford’s PPE Policy. The PPE shall ensure that hazardous substances and contaminated fluids and aerosols do not penetrate the employee’s mucous membranes or skin. The equipment and clothing shall be reasonably comfortable and shall not unduly encumber the employee’s movements necessary to perform the work. The equipment and clothing shall be compatible with the decontamination and disposal methods used.

4.3.3. Respiratory Protection [5199.1(d)(4)]

Research animal facilities must consult with EH&S to determine if respiratory protection is required for operations in restricted areas. Respiratory protection is required unless EH&S can demonstrate through objective evidence that engineering and work practice controls have eliminated the risk of disease transmission. [5199.1(d)(4)]

Respirator selection shall be based on the infectious disease hazard and on any hazardous substances that that may require respiratory protection. Respirators shall be used until work areas have been decontaminated. [5199.1(d)(4)]

Employees who work in enclosed areas shall use, at a minimum, elastomeric facepiece respirators or powered air purifying respirators (PAPR) with appropriate cartridges, unless EH&S has demonstrated through objective evidence, that such use is not necessary to protect employees.

4.3.4. Application of Toxic or Asphyxiant Gases [5199.1(d)(5)]

When conducted, the application of toxic or asphyxiant gases to occupiable areas will be conducted by outside contractors. The outside contractor is responsible for complying with 8
CCR 5199.1, including 8 CCR 5199.1(d)(5), which includes additional procedures for the application of toxic or asphyxiant gases the application.

Fumigation operations shall also comply with 8 CCR 5221-5223.

4.3.5. Disposal [5199.1(d)(6)]

Procedures for treatment and disposal of animal waste and contaminated PPE and clothing shall minimize employee exposure to zoonotic disease hazards, and shall be in accordance with applicable U.S. Environmental Protection Agency (EPA) and California EPA standards.

4.3.6. Decontamination [5199.1(d)(7)]

Research Animal Facilities shall ensure that personnel are properly decontaminated when leaving the restricted area and that contaminated clothing and equipment are appropriately decontaminated or disposed of. Decontaminated facilities shall include change rooms and shower facilities. If change rooms and shower facilities are not feasible, alternative effective measures shall be implemented.

4.3.7. Medical Services [5199.1(d)(8)]

A medical services program shall be provided to all personnel who enter the restricted area. The research animal facilities shall consult with the physician or other licensed health care professional (PLHCP) at SUOHC in the development of the medical services program. Medical services shall include, at a minimum, the following:

- Initial medical evaluation prior to the first entrance into a restricted area. The medical evaluation shall include respirator medical evaluation if respirator use is required.
- Surveillance for signs and symptoms of zoonotic disease. Employees exhibiting signs or symptoms of zoonotic disease and employees requesting referral shall be referred immediately to a PLHCP for follow-up evaluation.
- Surveillance for signs and symptoms of overexposures to hazardous substances as appropriate for substances present in the work operation. Employees exhibiting signs or symptoms of zoonotic disease and employees requesting referral shall be referred immediately to a PLHCP for follow-up evaluation.
- Provision of vaccination or prophylaxis as recommended by the Centers for Disease Control (CDC), California Department of Public Health (CDPH), the local health officer, or the PLHCP.
- Follow-up medical evaluations as recommended by the CDC, the CDPH, the local health officer, or the PLHCP.

The PLHCP shall provide the research animal facilities with a written report that contains only the following information:

- A written recommendation regarding the employee's ability to use the respirator.
- For vaccination or prophylaxis, whether the employee has been provided with vaccine and/or prophylaxis, and whether the employee is authorized to enter the restricted area.
• For referrals and follow-up medical evaluations, the PLHCP shall inform research animal facilities that the employee has received the evaluation, whether additional evaluation is required, and whether the employee is authorized to work in the restricted area.

4.3.8. Training [5199.1(d)(9)]

Personnel shall receive training upon initial assignment, when site conditions are substantially changes, and when hazards are newly introduced. Training shall include each of the following as they apply to the work operation:

• Identification and description of the zoonotic diseases that may be present in the work operation, and their signs and symptoms.
• The processes and procedures personnel will use in restricted areas or when dealing with infected animals or their waste.
• The research animal facilities safety program, including engineering and administrative controls, exposure monitoring and the results of exposure monitoring, the use of personal and respiratory protection equipment, cleaning and decontamination procedures, access to sanitation facilities and drinking water, and methods to control the risk of heat illness.
• The meaning of signs that will be used onsite.
• Hazard communications training
• The medical services program.

Training will be provided through a combination of Tier II and Tier III training.

4.4. Recordkeeping

Records of implementation of hazard identification, evaluation and control, and personnel training shall be created and maintained in accordance with the Stanford University Injury and Illness Prevention Program, which is available at http://www.stanford.edu/dept/EHS/prod/mainrencon/occhealth/iipp/iipp.pdf. [5199.1 (e)(1)]

Personnel exposure records, including the written zoonotic disease control procedures required by Section 4.3, records of entry into restricted areas, records of atmospheric testing, and records of exposures to hazardous substances shall be maintained for at least 30 years. [5199.1 (e)(2)]
5.2. Program Administrator

SUOH, DPS, and other operations as determined by the Biosafety Officer shall each designate a program administrator responsible for the establishment, implementation, and maintenance of written infection control procedures to control the risk of transmission of aerosol transmissible diseases (ATDs) for their operations. [5199(c)(1)]

For DPS, operations covered include the following:
- Police services provided during transport or detention of persons reasonably anticipated to be cases or suspected cases of ATDs. [5199(a)(1)(C)]
- Police services provided in conjunction with health care or public health operations. [5199(a)(1)(C)]

5.3. Written Infection Control Procedures

Written Infection Control Procedures shall include the following:
- Job categories in which employees have occupational exposure to ATDs. [5199(c)(1)]
- Procedures for cleaning and disinfection of work areas, vehicles, and equipment that may become contaminated with ATPs and pose an infection risk to employees. [5199(c)(1)]
- Source control procedures. These procedures shall: [5199(c)(2)]
  - Incorporate the recommendations contained in the Respiratory Hygiene/Cough Etiquette in Health Care settings, available at http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm. (DPS shall incorporate these recommendations to the extent reasonably practicable.)
  - Include the method of informing persons with whom employees will have contact of the source control methods.
- Procedures for the screening and referral of cases and suspected cases of AirIDs to appropriate facilities. [5199(c)(3)]
  - Referrals/transfers shall occur within 5 hours of the identification of the case or suspected case, unless the initial encounter occurs between 3:30 p.m. and 7:00 a.m. of the next day, in which case the referral/transfer must occur prior to 11:00 AM.
  - Sample criteria for screening that may be adopted in nonmedical settings can be found at http://www.dir.ca.gov/Title8/5199f.html
  - Seasonal influenza does not require referral.
- Procedures to communicate with employees, other employers, and the local health officer regarding the suspected or diagnosed infectious disease status of referred patients. These shall include procedures to receive information from the facility to which patients were referred and to provide necessary infection control information to employees who were exposed to the referred person. [5199(c)(4)]
- Procedures to reduce the risk of transmission of aerosol transmissible disease, to the extent feasible, during the period the person requiring referral is in the facility or is in contact with employees. These procedures shall include source control measures and, to the extent feasible: [5199(c)(5)]
  - Placement of the person requiring referral in a separate room or area
o Provision of separate ventilation or filtration in the room or area
o Employee use of respiratory protection when entering the room or area in which the person requiring referral is located, if that person is not compliant with source control measures

EXCEPTION: Law enforcement personnel who transport a person requiring referral in a vehicle need not use respiratory protection if all of the following conditions are met: [5199(c)(5)(C)]

- A solid partition separates the passenger area from the area where employees are located
- Written procedures are implemented that specify the conditions of operation, including the operation of windows and fans
- The airflow is tested (e.g., by the use of smoke tubes) in a representative vehicle (of the same model, year of manufacture, and partition design) under the specified conditions of operation, and finds that there is no detectable airflow from the passenger compartment to the employee area
- A record of the test results is maintained. Results shall be maintained in accordance with Section 10.2, below.

5.4. Training [5199(c)(7)]

Training shall be provided to all employees with occupational exposure. Training shall be provided at the time of initial assignment to tasks where occupational exposure may take place and at least annually. Additional training shall be provided when there are changes in the workplace or when there are changes in procedures that could affect worker exposure to ATPs. Training shall include the following:

- A general explanation of ATDs, including the signs and symptoms that require further medical evaluation.
- Screening methods and criteria for persons who require referral.
- Source control measures and how these measures will be communicated to persons the employees contact.
- Procedures for making referrals.
- Procedures for temporary risk reduction measures prior to transfer.
- Respiratory protection training, when respiratory protection is used.
- Procedures for the medical services provided by this ATD program, the methods of reporting exposure incidents, and procedures for providing employees with post-exposure evaluation.
- Information on vaccines available under this ATD program, including the seasonal influenza vaccine. For each vaccine, this information shall include the efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
- How employees can access this ATD program and written infection control procedures and how employees can participate in reviewing the effectiveness of the written infection control procedures.
- An opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter as it relates to the workplace that the training addresses and who is also knowledgeable in the written infection control procedures. Training not given in person shall provide for interactive questions to be answered within 24 hours by a knowledgeable person.
Training will be provided through a combination of Tier II and Tier III training.

5.5. Annual Review

Infection control procedures shall be reviewed annually by the administrator and by employees regarding the effectiveness of the program in their respective work areas. Any deficiencies found shall be corrected. [5199(c)(8)]

6. Blood Center

6.1. Laboratory [5199(f)]

6.1.1. Risk Assessment [5199(f)(2)]

The Biosafety Officer shall perform a risk assessment in accordance with the methodology included in Section II of the BMBL for each agent and procedure involving the handling of ATPs-L. The Biosafety Officer shall record the safe practices required for each evaluated agent/procedure in the Biosafety Plan.

6.1.2. Implementation of Control Measures [5199(f)(3)]

The Blood Center shall implement feasible engineering and work practice controls, in accordance with the risk assessment performed in section 6.1.1, to minimize employee exposures to ATPs-L. Where exposure still remains after the institution of engineering and work practice controls, the blood center shall provide, and ensure that employees use, personal protective equipment and, where necessary to control exposure, respiratory protection. Control measures shall be consistent with the recommendations in BMBL.

6.1.3. Written Local Biosafety Plan [5199(f)(4)]

The Blood Center shall establish, implement, and maintain an effective written local Biosafety Plan (BSP) to minimize employee exposure to ATPs-L that may be transmitted by laboratory aerosols. The BSP may be incorporated into an existing local Exposure Control Plan for bloodborne pathogens and shall do all of the following:

- Identify a biological safety officer(s) with the necessary knowledge, authority and responsibility for implementing the BSP. [5199(f)(4)(A)]
- Include a list of all job classifications in which all or some employees have occupational exposure, and a list of all tasks and procedures in which employees have occupational exposure. [5199(f)(4)(B)]
- Include a list of ATPs-L known or reasonably expected to be present in laboratory materials and the applicable biosafety measures. [5199(f)(4)(C)]
- Include a requirement that all incoming materials containing ATPs-L are to be treated as containing the virulent or wild-type pathogen, until procedures have been conducted at the laboratory to verify that a pathogen has been deactivated or attenuated. [5199(f)(4)(D)]
• Identify and describe the use of engineering controls, including containment equipment and procedures, to be used to minimize exposure to infectious or potentially infectious laboratory aerosols. [5199(f)(4)(E)]

• Establish safe handling procedures and prohibit practices, such as sniffing in vitro cultures, that may increase employee exposure to infectious agents. [5199(f)(4)(F)]

• Establish effective decontamination and disinfection procedures for laboratory surfaces and equipment. [5199(f)(4)(G)]

• Identify and describe the use of the appropriate personal protective equipment to be used to minimize exposure to infectious or potentially infectious laboratory aerosols. [5199(f)(4)(H)]

• Identify any operations or conditions in which respiratory protection will be required.

• Establish emergency procedures for uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility. These procedures shall include effective means of reporting such incidents to the local health officer. [5199(f)(4)(I)]

• Include procedures for communication of hazards and employee training that complies with Section 6.1.4. This shall include training in the Stanford University ATD Program, the Blood Center’s Biosafety Plan, and emergency procedures. [5199(f)(4)(L)]

• Include an effective procedure for obtaining the active involvement of employees in reviewing and updating the Biosafety Plan with respect to the procedures performed by employees in their respective work areas or departments on an annual (or more frequent) basis. [5199(f)(4)(M)]

• Include procedures for inspection of laboratory facilities, including an audit of biosafety procedures. These inspections shall be performed at least annually. Hazards found during the inspection, and actions taken to correct hazards, shall be recorded. [5199(f)(4)(O)]

6.1.4. Training [5199(i)]

Training shall be provided to all employees with occupational exposure as follows: [5199(i)(2)]

• At the time of initial assignment to tasks where occupational exposure may take place.

• At least annually thereafter, not to exceed 12 months from the previous training.

• When changes, such as introduction of new engineering or work practice controls, modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure or control measures. The additional training may be limited to addressing the new exposures or control measures.

Training shall include the following elements: [5199(i)(4)]

• An accessible copy of the regulatory text of 8CCR 5199 and an explanation of its contents. [5199(i)(4)(A)]

• A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation. [5199(i)(4)(B)]

• An explanation of the modes of transmission ATPs-L. [5199(i)(4)(C)]

• An explanation of the Stanford University ATD Program and the local Biosafety Plan, and the means by which the employee can obtain a copy of these written plans and how they can provide input as to its effectiveness. [5199(i)(4)(D)]
• An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATPs-L. [5199(i)(4)(E)]

• An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs-L including appropriate engineering and work practice controls, decontamination and disinfection procedures, and personal and respiratory protective equipment. [5199(i)(4)(F)]

• 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. [5199(i)(4)(G)]

• A description of the University’s TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI. [5199(i)(4)(H)]

• 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. [5199(i)(4)(J)]

• 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. [5199(i)(4)(K)]

The training program shall include an opportunity for interactive questions and answers with a person who is knowledgeable in the subject matter of the training as it relates to the workplace that the training addresses and who is also knowledgeable in the Stanford University ATD Program and the local biosafety plan.

6.1.5. Facility Design and Construction

The Biosafety Officer shall review plans for facility design and construction that will affect the control measures for ATPs-L. [(5199(f)(4)(N)]

7. Medical Services

7.1. General

Medical services are provided by SUOHC. SUOHC will refer personnel to other facilities, as appropriate.

7.2. Assessment for Latent Tuberculosis Infection (LTBI) [5199(c)(6)(C)]

Assessment for LTBI shall be made available to all personnel with occupational exposure. This includes DPS and SUOHC employees with occupational exposure, as well as laboratory personnel with occupational exposure if materials containing *M. Tuberculosis* will be present. [5199(h)(3)]

TB tests and other forms of TB assessment shall be provided at least annually, and more frequently, if applicable public health guidelines or the local health officer recommends more frequent testing. Employees with baseline positive TB test shall have an annual symptom screen. [5199(h)(3)(A)]
Personnel who experience a TB conversion shall be referred to a PLHCP knowledgeable about TB for evaluation. [5199(h)(3)(B)].

- The employer shall provide the PLHCP with a copy of this standard and the employee’s TB test records. If the employer has determined the source of the infection, the employer shall also provide any available diagnostic test results including drug susceptibility patterns related to the source patient.
- The employer shall request that the PLHCP, with the employee’s consent, perform any necessary diagnostic tests and inform the employee about appropriate treatment options.
- The employer shall 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 the employer of any infection control recommendations related to the employee’s activity in the workplace.
  - Make a recommendation to the employer regarding precautionary removal (Section 8.7, below).

Unless it is determined that the TB test conversion is not occupational, the employer shall investigate the circumstances of the conversion, and correct any deficiencies found during the investigation. The investigation shall be documented in accordance with Title 5199(j). [5199(h)(3)(D)]

7.3. Vaccinations

7.3.1. General

Recommended vaccinations shall be made available to all employees who have occupational exposure after the employee has received required training and within 10 working days of initial assignment unless any of the following applies: [5199(h)(5)(A)]

- The employee has previously received the recommended vaccination(s) and is not due to receive another vaccination dose.
- A PLHCP has determined that the employee is immune in accordance with applicable public health guidelines.
- The vaccine(s) is contraindicated for medical reasons.

Additional vaccine doses shall be made available to employees within 120 days of the issuance of new applicable public health guidelines recommending the additional dose. [5199(h)(5)(B)]

Participation in a prescreening serology program shall not be a prerequisite for receiving a vaccine, unless applicable public health guidelines recommend this prescreening prior to the administration of the vaccine. [5199(h)(5)(C)]

If an employee initially declines a vaccination, the employee may contact SUOHC and request the vaccination at a later date. If the employee is still occupationally exposed, the vaccine shall be made available within 10 working days. [5199(h)(5)(D)]

7.3.2. Seasonal Influenza Vaccine [5199(c)(6)(D)]
Seasonal influenza vaccine shall be made available to all employees with occupational exposure. This includes DPS and SUOHC employees with occupational exposure. The vaccine need not be provided outside of the period designated by the CDC for administration.

Each employee with occupational exposure who declines to accept the seasonal influenza vaccine shall sign the Seasonal Influenza Vaccination Declination Statement in Appendix C2

7.3.3. Vaccinations for Healthcare Workers  [5199(c)(6)(A)]

Vaccinations recommended by the California Department of Public Health, as listed in Appendix D, shall be made available to all SUOHC employees with occupational exposure.

Each SUOHC employee with occupational exposure who declines to accept a recommended and offered vaccination shall sign the statement in Appendix C1 for each declined vaccine. [5199(h)(5)(E)]

7.3.4. Vaccinations for Personnel in Laboratories

Laboratory personnel shall be provided with vaccines in accordance with the BMBL for the specific laboratory operations. [5199(h)(5)]

Each employee with occupational exposure who declines to accept a recommended and offered vaccination shall sign the statement in Appendix C1 for each declined vaccine. [5199(h)(5)(E)]

7.4. Post-Exposure Medical Evaluation

Procedures for post-exposure medical evaluation are described in Section 8.

7.5. Additional Medical Services

Additional medical services specific to laboratories and animal operations are discussed in Section 4.

8. Exposure Incidents to ATPs-L or RATDs

8.1. Reporting

All exposure incidents to ATPs-L or reportable ATDs (RATDs) must be reported on an SU-17 as soon as possible to allow for prompt investigation by the EH&S Biosafety Officer.

8.2. Analysis of Exposure Incidents  [5199(h)(6)(C)(1)]

An analysis of exposure incidents involving an ATP-L or RATD shall be conducted by the Biosafety Officer or other individual knowledgeable in the mechanisms of exposure to ATPs or ATPs-L within a timeframe reasonable for the disease⁵, but no later than 72 hours after receiving notification.

⁵ Exposure to some diseases, such as meningococcal disease, requires prompt prophylaxis of exposure individuals to prevent disease. Some diseases, such as varicella, have a limited window in which to administer vaccine to non-
The analysis shall record the following:
- Names and other appropriate identifiers of persons who were included in the analysis.
- The basis for any determination that an employee need not be included in post-exposure follow-up because the employee did not have a significant exposure or because a PLHCP determined that the employee is immune to the infection in accordance with applicable public health guidelines.
- The name of the person making the determination.
- The identity of any PLHCP or local health officer consulted in making the determination.

8.3. Notification of Employees [5199(h)(6)(C)(2)]

Within a timeframe that is reasonable for the specific disease, but in no case later than 96 hours of becoming aware of the potential exposure, employees who had significant exposure shall be notified of the date, time, and nature of the exposure.

8.4. Post-Exposure Medical Evaluation

Post-exposure medical evaluation shall be provided as soon as feasible to all employees who had a significant exposure. The evaluation shall be conducted by a PLCHP knowledgeable about the specific disease, including appropriate vaccination, prophylaxis, and treatment. For M. tuberculosis and for other pathogens where recommended by applicable public health guidelines, this shall include testing of the isolate from the source individual or material for drug susceptibility, unless the PLHCP determines that this is not feasible. [5199(h)(6)(C)(3)]

When SUOHC acts as the evaluating health care professional following an exposure incident, SUOHC shall advise the employee that the employee may refuse consent to vaccination, post-exposure evaluation, and follow-up from SUOHC. If consent is refused, a confidential vaccination, medical evaluation, or follow-up from a PLHCP other than SUOHC shall immediately be made available. [5199(h)(1)]

8.5. Exposure of Employees of Other Employers

To the extent that information is available in the employer’s records, the employer shall also determine whether employees of any other employers may have been exposed to the case or material. [5199(h)(6)(C)(5)]

The employer shall notify other employers within a time frame that is reasonable for the specific disease, but no later than 72 hours of becoming aware of the exposure incident of the nature, date, and time of the exposure, and shall provide the contact information for the diagnosing PLHCP. The identity of the source patient shall not be provided to other employers. [5199(h)(6)(C)(5)]

8.6. Information Provided to the PLHCP [5199(h)(7)]

immune contacts. Exposure to some diseases may create a need to temporarily remove an employee from certain duties during a potential period of communicability. For other diseases such as tuberculosis there may not be a need from immediate medical intervention, however prompt follow up is important to the success of identifying exposed employees.
The PLHCP shall be provided with the following information:

- A description of the exposed employee’s duties as they relate to the exposure incident.
- The circumstances under which the exposure incident occurred.
- 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.
- 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.

8.7. Precautionary Removal [5199(h)(8)]

For post-exposure evaluation or an evaluation of an employee’s TB conversion, the employer shall request from the PLHCP an opinion regarding whether precautionary removal from the employee’s regular assignment is necessary to prevent spread of the spread disease agent by the employee and what type of alternate work assignment may be provided. The employer shall request that the PLHCP convey the recommendation for precautionary removal via phone or fax and that the PLHCP document the recommendation in the written opinion. [5199(h)(8)(A)]

Where the PLHCP or local health officer recommends precautionary removal, the employer shall maintain the employee’s earnings, seniority, and all other employee rights and benefits, including the employee’s right to his or her former job status, as if the employee had not been removed from his or her job or otherwise medically limited. [5199(h)(8)(B)]

8.8. Written Opinion from the PLHCP [5199(h)(9)]

The employer shall obtain, and provide the employee with a copy of, the written opinion of the PLHCP within 15 working days of the completion of all medical evaluations required by this ATD Plan.

For TB conversions an all RATD and ATP-L exposure incidents, the written opinion shall be limited to the following information:

- The employee’s TB test status or applicable RATD test states for the exposure of concern.
- The employee’s infectivity status.
- 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.
- 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.
- Any recommendation for precautionary removal from the employee’s regular assignment.

All other findings or diagnoses shall remain confidential and shall not be included in the written report.

9. Respiratory Protection
The use of respiratory protection shall be consistent with the Stanford University Respiratory Protection Program, available at:

10. Recordkeeping

10.1. Training Records

Training records shall be maintained for 3 years from the date of the training. Records shall include the following: [5199(j)(2)]
- Date(s) of the training session(s)
- Contents or summary of the training session
- Names and qualifications of persons conducting the training or who are designated to respond to interactive questions
- Names and job titles of all persons attending the training sessions

10.2. Nondisposable Engineering Controls

Records of inspection, testing, and maintenance of nondisposable engineering controls including ventilation and other air handling systems, air filtration systems, containment equipment, biological safety cabinets, and waste treatment systems shall be maintained for a minimum of five years and shall include the following: [5199(j)(3)(F)]
- Names(s) and affiliation(s) of the persons(s) performing the test
- Inspection or maintenance
- Date
- Any significant findings and actions that were taken

Records of airflow tests of vehicles, if such tests are conducted, shall be maintained for a minimum of five years. Records shall include the following: [5199(j)(3)(F)] and [5199(c)(5)(C)]
- Name and affiliation of the person performing the test
- Date of the test
- Model and year of manufacture of the vehicle
- Partition design
- Any significant findings and actions, including whether there was detectable airflow from the passenger compartment to the employee area

10.3. Medical Records

Medical records for each employee with occupational exposure shall be maintained for at least the duration of employment plus 30 years [5199(j)(3)(B)].

10.4. Respiratory Protection Records

Records of the respiratory protection program shall be maintained in accordance with the Stanford University Respiratory Protection Program. [5199.1 (e)(4)] and [5199(j)(2)(G)]
10.5. Exposure Records

Records of exposure incidents shall be retained as employee exposure records. These records shall include: [5199(jj)(3)(B)]

- Date of the exposure incident.
- Names, and other employee identifiers, of employees who were included in the exposure evaluation.
- Disease or pathogen to which employees may have been exposed.
- Name and job title of the person performing the evaluation.
- Identity of any local health officer and/or PLHCP consulted.
- Date of the evaluation.
- Date of contact and contact information for any other employer who either notified the employer or was notified by the employer regarding potential employee exposure.

10.6. Additional Records

Additional records required to be kept by animal operations are discussed in Section 4.
Appendix A – Aerosol Transmissible Diseases/Pathogens

This appendix contains a list of diseases and pathogens which are to be considered aerosol transmissible pathogens or diseases for the purpose of 8 CCR 5199. Employers are required to provide the protections required by 8CCR 5199 according to whether the disease or pathogen requires airborne infection isolation or droplet precautions as indicated by the two lists below.

Diseases/Pathogens Requiring Airborne Infection Isolation

- Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease, e.g. Anthrax/Bacillus anthracis
- Avian influenza/Avian influenza A viruses (strains capable of causing serious disease in humans)
- 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
- Measles (rubeola)/Measles virus
- Monkeypox/Monkeypox virus
- Novel or unknown pathogens
- Severe acute respiratory syndrome (SARS)
- Smallpox (variola)/Variola virus
- Tuberculosis (TB)/Mycobacterium tuberculosis -- Extrapulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected
- Any other disease for which public health guidelines recommend airborne infection isolation

Diseases/Pathogens Requiring Droplet Precautions

- Diphtheria pharyngeal
- Epiglottitis, due to Haemophilus influenzae type b
- Haemophilus influenzae Serotype b (Hib) disease/Haemophilus influenzae serotype b -- Infants and children
- Influenza, human (typical seasonal variations)/influenza viruses
- Meningitis
  - Haemophilus influenzae, type b known or suspected
  - Neisseria meningitidis (meningococcal) known or suspected
- Meningococcal disease sepsis, pneumonia (see also meningitis)
- Mumps (infectious parotitis)/Mumps virus
- Mycoplasmal pneumonia
- Parvovirus B19 infection (erythema infectiosum)
- Pertussis (whooping cough)
- Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus
- Pneumonia
  - Adenovirus
  - Haemophilus influenzae Serotype b, infants and children
  - Meningococcal
  - Mycoplasma, primary atypical
  - Streptococcus Group A
- Pneumonic plague/Yersinia pestis
- Rubella virus infection (German measles)/Rubella virus
• Severe acute respiratory syndrome (SARS)
• Streptococcal disease (group A streptococcus)
  o Skin, wound or burn, Major
  o Pharyngitis in infants and young children
  o Pneumonia
  o Scarlet fever in infants and young children
  o Serious invasive disease
• Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses (airborne infection isolation and respirator use may be required for aerosol-generating procedures)
• Any other disease for which public health guidelines recommend droplet precautions
Appendix B – Aerosol Transmissible Pathogens – Laboratory

This appendix contains a list of agents that, when reasonably anticipated to be present, require a laboratory to comply with 8 CCR 5199 for laboratory operations by performing a risk assessment and establishing a biosafety plan that includes appropriate control measures as identified in the standard.

- **Adenovirus** (in clinical specimens and in cultures or other materials derived from clinical specimens)
- **Arboviruses**, unless identified individually elsewhere in this list (large quantities or high concentrations* of arboviruses for which CDC recommends BSL-2, e.g., dengue virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arboviruses for which CDC recommends BSL-3 or higher, e.g., Japanese encephalitis, West Nile virus, Yellow Fever)
- **Arenaviruses** (large quantities or high concentrations of arenaviruses for which CDC recommends BSL-2, e.g., Pichinde virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arenaviruses for which CDC recommends BSL-3 or higher, e.g., Flexal virus)
- **Bacillus anthracis** (activities with high potential for aerosol production**, large quantities or high concentrations, screening environmental samples from *b. anthracis*-contaminated locations)
- **Blastomyces dermatitidis** (sporulating mold-form cultures, processing environmental materials known or likely to contain infectious conidia)
- **Bordetella pertussis** (aerosol generation, or large quantities or high concentrations)
- **Brucella abortus, B. canis, B. "maris", B. melitensis, B. suis** (cultures, experimental animal studies, products of conception containing or believed to contain pathogenic *Brucella* spp.)
- **Burkholderia mallei, B. pseudomallei** (potential for aerosol or droplet exposure, handling infected animals, large quantities or high concentrations)
- Cercopithecine herpesvirus (see Herpesvirus simiae)
- **Chlamydia pneumoniae** (activities with high potential for droplet or aerosol production, large quantities or high concentrations)
- **Chlamydia psittaci** (activities with high potential for droplet or aerosol production, large quantities or high concentrations, non-avian strains, infected caged birds, necropsy of infected birds and diagnostic examination of tissues or cultures known to contain or be potentially infected with *C. psittaci* strains of avian origin)
- **Chlamydia trachomatis** (activities with high potential for droplet or aerosol production, large quantities or high concentrations, cultures of lymphogranuloma venereum (LGV) serovars, specimens known or likely to contain *C. trachomatis*)
- **Clostridium botulinum** (activities with high potential for aerosol or droplet production, large quantities or high concentrations)
- **Coccidioides immitis, C. posadasii** (sporulating cultures, processing environmental materials known or likely to contain infectious arthroconidia, experimental animal studies involving exposure by the intranasal or pulmonary route)
- **Corynebacterium diphtheriae**
- **Coxiella burnetti** (inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies, animal studies with infected arthropods, necropsy of infected animals, handling infected tissues)
- Crimean-Congo haemorrhagic fever virus
- **Cytomegalovirus**, human (viral production, purification, or concentration)
- Eastern equine encephalomyelitis virus (EEEV) (clinical materials, infectious cultures, infected animals or arthropods)
- Ebola virus
- Epstein-Barr virus (viral production, purification, or concentration)
- **Escherichia coli**, shiga toxin-producing only (aerosol generation or high splash potential)
- Flexal virus
- *Francisella tularensis* (suspect cultures—including preparatory work for automated identification systems, experimental animal studies, necropsy of infected animals, high concentrations of reduced-virulence strains)
- Guanarito virus
- *Haemophilus influenzae, type b*
- Hantaviruses (serum or tissue from potentially infected rodents, potentially infected tissues, large quantities or high concentrations, cell cultures, experimental rodent studies)
- *Helicobacter pylori* (homogenizing or vortexing gastric specimens)
- Hemorrhagic fever -- specimens from cases thought to be due to dengue or yellow fever viruses or which originate from areas in which communicable hemorrhagic fever are reasonably anticipated to be present
- Hendra virus
- Hepatitis B, C, and D viruses (activities with high potential for droplet or aerosol generation, large quantities or high concentrations of infectious materials)
- Herpes simplex virus 1 and 2
- Herpesvirus simiae (B-virus) (consider for any material suspected to contain virus, mandatory for any material known to contain virus, propagation for diagnosis, cultures)
- *Histoplasma capsulatum* (sporulating mold-form cultures, propagating environmental materials known or likely to contain infectious conidia)
- Human herpesviruses 6A, 6B, 7, and 8 (viral production, purification, or concentration)
- Influenza virus, non-contemporary human (H2N2) strains, 1918 influenza strain, highly pathogenic avian influenza (HPAI) (large animals infected with 1918 strain and animals infected with HPAI strains in ABSL-3 facilities, loose-housed animals infected with HPAI strains in BSL-3-Ag facilities)
- Influenza virus, H5N1 - human, avian
- Junin virus
- Kyasanur forest disease virus
- Lassa fever virus
- *Legionella pneumophila*, other legionella-like agents (aerosol generation, large quantities or high concentrations)
- Lymphocytic choriomeningitis virus (LCMV) (field isolates and clinical materials from human cases, activities with high potential for aerosol generation, large quantities or high concentrations, strains lethal to nonhuman primates, infected transplantable tumors, infected hamsters)
- Machupo virus
- Marburg virus
- Measles virus
- Monkeypox virus (experimentally or naturally infected animals)
- Mumps virus
- *Mycobacterium tuberculosis complex* (*M. africanum*, *M. bovis*, *M. caprae*, *M. microti*, *M. pinnipedii*, *M. tuberculosis*) (aerosol-generating activities with clinical specimens, cultures, experimental animal studies with infected nonhuman primates)
- *Mycobacteria* spp. other than those in the *M. tuberculosis* complex and *M. leprae* (aerosol generation)
- *Mycoplasma pneumoniae*
- *Neisseria gonorrhoeae* (large quantities or high concentrations, consider for aerosol or droplet generation)
- *Neisseria meningitidis* (activities with high potential for droplet or aerosol production, large quantities or high concentrations)
- Nipah virus
- Omsk hemorrhagic fever virus
- Parvovirus B19
- Prions (bovine spongiform encephalopathy prions, only when supported by a risk assessment)
- Rabies virus, and related lyssaviruses (activities with high potential for droplet or aerosol production, large quantities or high concentrations)
• Retroviruses, including Human and Simian Immunodeficiency viruses (HIV and SIV) (activities with high potential for aerosol or droplet production, large quantities or high concentrations)
• Rickettsia prowazekii, Orientia (Rickettsia) tsutsugamushi, R. typhi (R. mooseri), Spotted Fever Group agents (R. akari, R. australis, R. conorii, R. japonicum, R. rickettsii, and R. siberica) (known or potentially infectious materials; inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies with infected arthropods)
• Rift valley fever virus (RVFV)
• Rubella virus
• Sabia virus
• Salmonella spp. other than S. typhi (aerosol generation or high splash potential)
• Salmonella typhi (activities with significant potential for aerosol generation, large quantities)
• SARS coronavirus (untreated specimens, cell cultures, experimental animal studies)
• Shigella spp. (aerosol generation or high splash potential)
• Streptococcus spp., group A
• Tick-borne encephalitis viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis, Russian spring and summer encephalitis)
• Vaccinia virus
• Varicella zoster virus
• Variola major virus (Smallpox virus)
• Variola minor virus (Alastrim)
• Venezuelan equine encephalitis virus (VEEV) (clinical materials, infectious cultures, infected animals or arthropods)
• West Nile virus (WNV) (dissection of field-collected dead birds, cultures, experimental animal and vector studies)
• Western equine encephalitis virus (WEEV) (clinical materials, infectious cultures, infected animals or arthropods)
• Yersinia pestis (antibiotic resistant strains, activities with high potential for droplet or aerosol production, large quantities or high concentrations, infected arthropods, potentially infected animals)

* ‘Large quantities or high concentrations’ refers to volumes or concentrations considerably in excess of those typically used for identification and typing activities. A risk assessment must be performed to determine if the quantity or concentration to be used carries an increased risk, and would therefore require aerosol control.

** ‘activities with high potential for aerosol generation’ include centrifugation
Appendix C1 – Vaccination Declination Statement

The employer shall ensure that employees who decline to accept a recommended vaccination offered by the employer sign and date the following statement as required by 8 CCR 5199(h)(5)(E):

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 ______________________, 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.

__________________________  __________________
Employee Signature                  Date
Appendix C2 – Seasonal Influenza Vaccination Declination Statement

The employer shall ensure that employees who decline to accept the seasonal influenza vaccination offered by the employer sign and date the following statement as required by 8 CCR 5199(h)(10):

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.

.Employee Signature  Date
### Appendix D – Aerosol Transmissible Disease Vaccination Recommendations for Susceptible Health Care Workers

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>One dose annually</td>
</tr>
<tr>
<td>Measles</td>
<td>Two doses</td>
</tr>
<tr>
<td>Mumps</td>
<td>Two doses</td>
</tr>
<tr>
<td>Rubella</td>
<td>One dose</td>
</tr>
<tr>
<td>Tetanus, Diptheria, and Acellular Pertussis (Tdap)</td>
<td>One dose, booster as recommended</td>
</tr>
<tr>
<td>Varicella-zoster (VZV)</td>
<td>Two doses</td>
</tr>
</tbody>
</table>

Source: California Department of Public Health, Immunization Branch
Immunity should be determined in consultation with *Epidemiology and Prevention of Vaccine-Preventable Diseases.*
Appendix E – Definitions

**Aerosol transmissible disease (ATD) or aerosol transmissible pathogen (ATP).** A disease or pathogen for which droplet or airborne precautions are required, as listed in Appendix A.

**Aerosol transmissible pathogen - laboratory (ATP-L).** A pathogen that meets one of the following criteria: (1) the pathogen appears on the list in Appendix B, (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.

**Airborne infection isolation (AII).** Infection control procedures as described in Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. These procedures are designed to reduce the risk of transmission of airborne infectious pathogens, and apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.

**Airborne infectious disease (AirID).** Either: (1) an aerosol transmissible disease transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the disease agent for which AII is recommended by the CDC or CDPH, as listed in Appendix A, or (2) the disease process caused by a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that the pathogen is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.

**Airborne infectious pathogen (AirIP).** Either: (1) an aerosol transmissible pathogen transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the infectious agent, and for which the CDC or CDPH recommends AII, as listed in Appendix A, or (2) a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that it is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.

**Animal Biosafety Level 3 (ABSL-3).** Compliance with the criteria for work practices, safety equipment, and facility design and construction recommended by the CDC in Biosafety in Microbiological and Biomedical Laboratories for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission and agents causing serious or potentially lethal disease.

**Animals infected with zoonotic ATPs.** Animals that (1) have been diagnosed with a zoonotic ATP through recognized testing methods or (2) meet the clinical definition of a suspect case of infection with a zoonotic ATP or (3) have been identified by the CDFA, CDFG, USDA, or USDOI as requiring isolation, quarantine, or destruction due to suspected or confirmed infection.

**Animal waste.** Animal carcasses, excrement, contaminated litter, or debris from the bodies of animals, such as feathers or dander.

**Biological safety officer(s).** A person who is qualified by training and/or experience to evaluate hazards associated with laboratory procedures involving ATPs-L, who is knowledgeable about the facility
biosafety plan, and who is authorized by the employer to establish and implement effective control measures for laboratory biological hazards.

**Biosafety level 3.** Compliance with the criteria for laboratory practices, safety equipment, and facility design and construction recommended by the CDC in Biosafety in Microbiological and Biomedical Laboratories for laboratories in which work is done with indigenous or exotic agents with a potential for aerosol transmission and which may cause serious or potentially lethal infection.

**Biosafety in Microbiological and Biomedical Laboratories (BMBL).** Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, CDC and National Institutes for Health, 2007, which is hereby incorporated by reference for the purpose of establishing biosafety requirements in laboratories.

**Biosecurity procedures.** Control measures, such as traffic control, disinfection, and isolation, that are implemented to reduce the risk of transmission of infection into, from, or within an establishment. The purpose of biosecurity measures is to prevent direct or indirect animal-to-animal transmission of zoonotic ATPs, release of pathogens into the environment, and infection of people who may come into contact with animals or areas where animals are housed, or with debris from those areas. The specific biosecurity measures necessary depend on the type of operation conducted by the employer. Typically, no provision for biosecurity other than the use of common sanitation measures is required for incidental removal of animal carcasses or other wastes, unless the activity may result in the introduction of pathogens into areas where animals are kept or housed, or unless the animal is the subject of an applicable alert or disease control order.

**CDFA.** California Department of Food and Agriculture.

**CDFG.** California Department of Fish and Game.

**CDC.** United States Centers for Disease Control and Prevention.

**CDPH.** California Department of Public Health and its predecessor the California Department of Health Services.

**Case.** Either of the following:

(1) A person who has been diagnosed by a health care provider who is lawfully authorized to diagnose, using clinical judgment or laboratory evidence, to have a particular disease or condition.

(2) A person who is considered a case of a disease or condition that satisfies the most recent communicable disease surveillance case definitions established by the CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements.

**CTCA.** The California Tuberculosis Controllers Association.

**Decontamination.** The removal of hazardous substances from employees and their equipment to the extent necessary to preclude the occurrence of foreseeable adverse health effects.

**Immediately dangerous to life or health (IDLH).** An atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual’s ability to escape.
Local health officer. The health officer for the local jurisdiction responsible for receiving and/or sending reports of communicable diseases, as defined in Title 17 of the California Code of Regulations.

Droplet precautions. Infection control procedures as described in Guideline for Isolation Precautions designed to reduce the risk of transmission of infectious agents through contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 mm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism.

Drug treatment program. A program that is (A) licensed pursuant to Chapter 7.5 (commencing with Section 11834.01), Part 2, Division 10.5 of the Health and Safety Code; or Chapter 1 (commencing with Section 11876), Part 3, Article 3, Division 10.5 of the Health and Safety Code; or (B) certified as a substance abuse clinic or satellite clinic pursuant to Section 51200, Title 22, CCR, and which has submitted claims for Medi-Cal reimbursement pursuant to Section 51490.1, Title 22, CCR, within the last two calendar years or (C) certified pursuant to Section 11831.5 of the Health and Safety Code.

Exposure incident. An event in which all of the following have occurred: (1) An employee has been exposed to an individual who is a case or suspected case of a reportable ATD, or to a work area or to equipment that is reasonably expected to contain ATPs associated with a reportable ATD; and (2) The exposure occurred without the benefit of applicable exposure controls required by this section, and (3) It reasonably appears from the circumstances of the exposure that transmission of disease is sufficiently likely to require medical evaluation.

Exposure incident (laboratory). A significant exposure to an aerosol containing an ATP-L, without the benefit of applicable exposure control measures required by this section.

Health care provider. A physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

Health care worker. A person who works in a health care facility, service or operation, or who has occupational exposure in a public health service, such as communicable disease contact tracing or screening programs that are reasonably anticipated to be provided to cases or suspected cases of aerosol transmissible diseases.

High hazard procedures. Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications, and pulmonary function testing. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens.

Initial treatment. Treatment provided at the time of the first contact a health care provider has with a person who is potentially an AirID case or suspected case. Initial treatment does not include high hazard procedures.
**Laboratory.** A facility or operation in a facility where the manipulation of specimens or microorganisms is performed for the purpose of diagnosing disease or identifying disease agents, conducting research or experimentation on microorganisms, replicating microorganisms for distribution or related support activities for these processes.

**Latent TB infection (LTBI).** Infection with *M. tuberculosis* in which bacteria are present in the body, but are inactive. Persons who have LTBI but who do not have TB disease are asymptomatic, do not feel sick and cannot spread TB to other persons. They typically react positively to TB tests.

**Local health officer.** The health officer for the local jurisdiction responsible for receiving and/or sending reports of communicable diseases, as defined in Title 17, CCR.

NOTE: Title 17, Section 2500 requires that reports be made to the local health officer for the jurisdiction where the patient resides.

**M. tuberculosis.** *Mycobacterium tuberculosis* complex, which includes *M. tuberculosis*, *M. bovis*, *M. africanum*, and *M. microti*. *M. tuberculosis* is the scientific name of the group of bacteria that cause tuberculosis.

**NIOSH.** The Director of the National Institute for Occupational Safety and Health, CDC, or his or her designated representative.

**Non-medical transport.** The transportation by employees other than health care providers or emergency medical personnel during which no medical services are reasonably anticipated to be provided.

**Novel or unknown ATP.** A pathogen capable of causing serious human disease meeting the following criteria:

1. There is credible evidence that the pathogen is transmissible to humans by aerosols; and
2. The disease agent is:
   a. A newly recognized pathogen, or
   b. A newly recognized variant of a known pathogen and there is reason to believe that the variant differs significantly from the known pathogen in virulence or transmissibility, or
   c. A recognized pathogen that has been recently introduced into the human population, or
   d. A not yet identified pathogen.

NOTE: Variants of the human influenza virus that typically occur from season to season are not considered novel or unknown ATPs if they do not differ significantly in virulence or transmissibility from existing seasonal variants. Pandemic influenza strains that have not been fully characterized are novel pathogens.
**Occupational exposure.** Exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATPs-L if protective measures are not in place. In this context, “elevated” means higher than what is considered ordinary for employees having direct contact with the general public outside of the facilities, service categories and operations listed in 8 CCR 5199(a)(1). Occupational exposure is presumed to exist to some extent in each of the facilities, services and operations listed in 8 CCR 5199(a)(1). Whether a particular employee has occupational exposure depends on the tasks, activities, and environment of the employee, and therefore, some employees of a covered employer may have no occupational exposure. For example, occupational exposure typically does not exist where a hospital employee works only in an office environment separated from patient care facilities, or works only in other areas separate from those where the risk of ATD transmission, whether from patients or contaminated items, would be elevated without protective measures. It is the task of employers covered by this standard to identify those employees who have occupational exposure so that appropriate protective measures can be implemented to protect them as required. Employee activities that involve having contact with, or being within exposure range of cases or suspected cases of ATD, are always considered to cause occupational exposure. Similarly, employee activities that involve contact with, or routinely being within exposure range of, populations served by correctional facilities and other facilities that house inmates or detainees, homeless shelters, or drug treatment programs are considered to cause occupational exposure. Employees working in laboratory areas in which ATPs-L are handled or reasonably anticipated to be present are also considered to have occupational exposure.

Occupational exposure also includes reasonably anticipated work exposure to a source of zoonotic ATPs under conditions that, without the use of protective measures, create a significant risk of contracting the disease caused by the pathogen. Examples of such conditions include: conducting diagnostic sampling of animals reasonably suspected of infection, performing animal husbandry activities with flocks quarantined due to an increased risk of infection with zoonotic ATPs, and disposing of infected animal carcasses or their wastes.

**Oxygen deficient atmosphere.** An atmosphere with an oxygen content below 19.5% by volume.

**Physician or other licensed health care professional (PLHCP).** An individual whose legally permitted scope or practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by this section.

**Public health guidelines.** (1) In regards to tuberculosis, applicable guidelines published by the CTCA and/or CDPH as follows:

(A) Guidelines for Tuberculosis (TB) Screening and Treatment of Patients with Chronic Kidney Disease (CKD), Patients Receiving Hemodialysis (HD), Patients Receiving Peritoneal Dialysis (PD), Patients Undergoing Renal Transplantation and Employees of Dialysis Facilities, May 18, 2007.

(B) Guidelines for the Treatment of Active Tuberculosis Disease, April 15, 2003 including related material: Summary of Differences Between 2003 California and National Tuberculosis Treatment Guidelines, 2004, Amendment to Joint CDHS/CTCA Guidelines for the Treatment of Active Tuberculosis Disease, May 12, 2006, Appendix 3 - Algorithm for MDR-TB Cases and Hospital Discharge, May 12, 2006.
(C) Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, May 12, 2006.


(E) Guidelines for Mycobacteriology Services in California, April 11, 1997.

(F) Guidelines for the Placement or Return of Tuberculosis Patients into High Risk Housing, Work, Correctional, or In-Patient Settings, April 11, 1997.

(G) Contact Investigation Guidelines, November 12, 1998.


(J) Guidelines for Reporting Tuberculosis Suspects and Cases in California, October 1997.

(K) CTCA recommendations for serial TB testing of Health Care Workers (CA Licensing and Certification), September 23, 2008.

(2) In regards to vaccine-preventable diseases, the publication cited in the definition of Epidemiology and Prevention of Vaccine-Preventable Diseases.

(3) In regards to any disease or condition not addressed by the above guidelines, recommendations made by the CDPH or the local health officer pursuant to authority granted under the Health and Safety Code and/or Title 17, California Code of Regulations.

**Referral.** The directing or transferring of a possible ATD case to another facility, service or operation for the purposes of transport, diagnosis, treatment, isolation, housing or care.

**Referring employer.** Any employer that operates a facility, service, or operation in which there is occupational exposure and which refers AirID cases and suspected cases to other facilities. Referring facilities, services and operations do not provide diagnosis, treatment, transport, housing, isolation or management to persons requiring AirID. General acute care hospitals are not referring employers. Law enforcement, corrections, public health, and other operations that provide only non-medical transport for referred cases are considered referring employers if they do not provide diagnosis, treatment, housing, isolation or management of referred cases.

**Reportable aerosol transmissible disease (RATD).** A disease or condition which a health care provider is required to report to the local health officer, in accordance with Title 17 CCR, Division 1, Chapter 4, and which meets the definition of an aerosol transmissible disease (ATD).

**Respirator.** A device which has met the requirements of 42 CFR Part 84, has been designed to protect the wearer from inhalation of harmful atmospheres, and has been approved by NIOSH for the purpose for which it is used.

Screening (health care provider). The initial assessment of persons who are potentially AirID or ATD cases by a health care provider in order to determine whether they need airborne infection isolation or need to be referred for further medical evaluation or treatment to make that determination. Screening does not include high hazard procedures.

Screening (non health care provider). The identification of potential ATD cases through readily observable signs and the self-report of patients or clients. Screening does not include high hazard procedures.

Significant exposure. An exposure to a source of ATPs or 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 PLHCP.

Source control measures. The use of procedures, engineering controls, and other devices or materials to minimize the spread of airborne particles and droplets from an individual who has or exhibits signs or symptoms of having an ATD, such as persistent coughing.

Susceptible person. A person who is at risk of acquiring an infection due to a lack of immunity as determined by a PLHCP in accordance with applicable public health guidelines.

Suspected case. Either of the following:

(1) A person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence, to probably have a particular disease or condition listed in Appendix A.

(2) A person who is considered a probable case, or an epidemiologically-linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements as applied to a particular disease or condition listed in Appendix A.

TB conversion. A change from negative to positive as indicated by TB test results, based upon current CDC or CDPH guidelines for interpretation of the TB test.

Test for tuberculosis infection (TB test). Any test, including the tuberculin skin test and blood assays for M. Tuberculosis (BAMT) such as interferon gamma release assays (IGRAs) which: (1) has been approved by the Food and Drug Administration for the purposes of detecting tuberculosis infection, and (2) is recommended by the CDC for testing for TB infection in the environment in which it is used, and (3) is administered, performed, analyzed and evaluated in accordance with those approvals and guidelines.

NOTE: Where surveillance for LTBI is required by Title 22, CCR, the TB test must be approved for this use by the CDPH.

Tuberculosis (TB). A disease caused by M. tuberculosis.
**Wildlife.** Wild birds and other animals that are not domesticated, including their remains and wastes.

**Zoonotic aerosol transmissible pathogen (Zoonotic ATP).** A disease agent that is transmissible from animals to humans by aerosol, and is capable of causing human disease. Zoonotic ATPs include pathogens that are classified as transmissible either by droplets or by an airborne route.
Appendix F – Resources

External Resources

- 8 CCR 5221 – Fumigation: General, http://www.dir.ca.gov/Title8/5221.html
- 8 CCR 5222 – Fumigation in Vaults and Chambers, http://www.dir.ca.gov/Title8/5222.html
- 8 CCR 5223 – Fumigation in Buildings or Rooms Other Than Fumigation Vaults or Chambers, http://www.dir.ca.gov/Title8/5223.html

Stanford Resources