Aerosol Transmissible Diseases Program

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Revised by
Kathryn Nobrega, CIH
Linh Phan, PhD
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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 School of Medicine Clinical and Translational Research Unit (CTRU) [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
- Other operations, as needed, that are identified by the Biosafety Officer

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2 http://www.dir.ca.gov/Title8/5199.html
3 http://www.dir.ca.gov/Title8/5199-1.html
3. **Research Laboratory Operations Involving ATPs or Zoonotic ATPs [5199(f)]**

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

Laboratories at Stanford that work with Aerosol Transmissible Pathogens-Laboratory (ATPs-L) or zoonotic ATPs must submit an application to the Administrative Panel on Biosafety (APB) for the possession, storage, transfer, and use of the biohazardous materials.

An ATP-L is a pathogen that meets at least one of the following criteria:
- The pathogen appears on the list in the Appendix B of this document.
- The *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) recommends biosafety level 3 or above for the pathogen.
- The pathogen is a novel or unknown pathogen. A novel or an unknown pathogen is the one capable of causing serious human disease meeting the following criteria:
  - There is credible evidence that the pathogen is transmissible to humans by aerosols; and
  - 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.
- The biological safety officer recommends biosafety level 3 or above for the pathogen.

A zoonotic ATD is 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.

The APB application must be reviewed and approved by the APB before a laboratory 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 to determine appropriate control measures and personal protective equipment (PPE), including respiratory protection 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)]

Laboratories 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 Principal Investigator/Lab Supervisor is responsible for implementing the written BSP. The BSP shall be reviewed at least annually by the Stanford University Biosafety Officer and by employees regarding the effectiveness of the program in the respective work area. Deficiencies found shall be corrected. The review(s) shall be documented in writing. 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. The use of respiratory protection must be in accordance with the Stanford University Respiratory Protection Program.
- 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
3.4. 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. Hazards found during the inspection, and actions taken to correct hazards, shall be recorded.

3.5. 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.

3.6. 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 and applicable source control. [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)]

• Training meeting the requirements of the Stanford University Respiratory Protection program for employees whose assignment includes the use of a respirator. 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.

3.7. Respiratory Protection [5199(g)]

• The use of respiratory protection shall be consistent with the Stanford University Respiratory Protection Program, available at: https://ehs.stanford.edu/topic/general-workplace-safety/respiratory-protection-program

• Respirator Selection: [5199(g)(3)]
  o Respirators used in laboratory operations to protect against infectious aerosols shall be selected in accordance with the risk assessment and biosafety plan.
  o The employer shall select and provide a respirator that is at least as effective as an N95 filtering facepiece respirator (FFR), but if the employer determines that higher level protection is necessary for a particular pathogen or exposure scenario, then the employer shall provide a more protective respirator.
  o If protection is required from both ATPs and bloodborne pathogens that transmit through mucous membrane exposure, then the employee should use a surgical N95 respirator, which is resistant to fluids, or a combination of respirator and face shield or other PPE.
  o Where respirators are necessary to protect the user from other hazards, including uncontrolled release of microbiological spores, or exposure to chemical or radiological agents, respirator selection shall be made in accordance with Stanford University Respiratory Protection program.

• The employer shall provide, and ensure that employees use, a respirator selected in accordance with subsection respirator selection and Stanford University Respiratory Protection program when the employee does any of the following: [5199(g)(4)]
  o Repairs, replaces, or maintains air systems or equipment that may contain or generate aerosolized pathogens.
  o Performs a task for which the BSP or APB application requires the use of respirators.

• See section 8 Respiratory Protection in this document for further information.

3.8. Medical Service [5199(h)]

See Section 6 Medical Services and Section 7 Exposure Incidents to ATPs-L or RATDs in this
3.9. Recordkeeping [5199(j)]

See section 9 Recordkeeping in this document.


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, biosafety 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. These facilities shall also comply with subsection Recordkeeping [5199.1(e)]. Where the risk assessment determines that ABSL-3 or above practices are required the employer shall comply with subsection [5199.1(d)]. [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 https://ehs.stanford.edu/topic/animal-safety/laboratory-animal-occupational-health-program


Prior to any work operations involving in handling, transporting, or disposing of animals infected with zoonotic ATPs, or the cleaning and disinfection of areas used, or previously used, to contain such animals or their wastes, any 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 from the animals to employees. These procedures shall be onsite at all times when employees are present, and shall be maintained as an employee exposure record in accordance with Title 8 CCR 3204 Access to Employee Exposure and Medical Records. [5199.1(d)]

Consult with the Biosafety Officer, as needed, to determine the likelihood of wildlife being infected with ATPs-Zoonotic.
These written 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
  - Respiratory protection
  - Personal protective equipment and protective clothing
  - Procedures for the application of toxic or asphyxiant gases, if such gases are to be used in the operation
  - Decontamination procedures
  - Disposal of animal waste and contaminated personal protective equipment
  - Medical services
  - Training
  - Recordkeeping

- 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.

These records shall be maintained and made available in accordance with subsection 4.4 Recordkeeping in this document.

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)]

The use of respiratory protection shall be consistent with the Stanford University Respiratory Protection Program, available at: https://ehs.stanford.edu/topic/general-workplace-safety/respiratory-protection-program

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 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. The employer shall provide and ensure that employees use appropriate eye protection, unless employees use full facepiece respirators or PAPRs that provide eye protection.

The following procedures shall include the use of a respirator at least as effective as an N95 FFR in accordance with Stanford University Respiratory Protection Program whenever: [5199.1(b)(3)]

- There is an increased potential of exposure to infectious aerosols, such as when handling animals in an enclosed or indoor area.
- Responding to a mortality event involving a significant number of animals, or
- There are animal-related dusts in the environment that are reasonably likely to be an aerosol infection hazard to 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 CCR 5199.1, including Title 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. Decontamination facilities shall include change rooms and shower facilities that meet the requirements of Title 8 CCR 3360-3368. If change rooms and shower facilities are not feasible, alternative effective measures shall be implemented for decontamination and changing clothes that protect employees from infectious materials and hazardous substances that may be present on their clothing or their person.

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, and EH&S shall further investigate the source of the potential over-exposure and take corrective measures, as needed.
- 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 in accordance with Title 8 CCR 5194.
- The medical services program at SUOHC.

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 https://ehs.stanford.edu/topic/general-workplace-safety/injury-and-illness-prevention-program [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 in accordance with Title 8 CCR 3204. [5199.1 (e)(2)]

Employee medical records shall be maintained in a confidential manner in accordance with 8 CCR 3204. [5199.1 (e)(3)]

Records of the respiratory protection program shall be established, maintained, and made available in accordance with Stanford University Respiratory Protection program and Title 8 CCR 3204 [5199.1 (e)(4)].

Employee medical records required by this section shall be provided upon request for examination and/or copying, in accordance with Title 8 CCR 3204 to the subject employee, to anyone having the subject employee’s written consent, and to the Chief, NIOSH, and the local health officer. [5199.1 (e)(5)(A)]

All other records shall be made available upon request for examination and/or copying to employees, employee representatives, the Chief, NIOSH, and the local health officer. [5199.1 (e)(5)(B)]

5. Stanford University Occupational Health Clinic, Department of Public Safety, and Clinical and Translational Research Unit

5.1. General

SUOHC, DPS, and CTRU are considered “referring employers” within the scope and application of 8 CCR 5199.

For SUOHC and CTRU, operations meet all of the following conditions:
- Screen persons for airborne infectious diseases (AirID) [5199(a)(3)(A)1.]
- Refer any person identified as a case or suspected case of AirID [5199(a)(3)(A)2.]
- Do not intend to provide further medical services to AirID cases and suspected cases beyond first aid, initial treatment, or screening and referral. [5199(a)(3)(A)3.]
- Do not provide transport, housing, or airborne infection isolation to any person identified as an AirID case or suspected case, unless the transport provided is only nonmedical transport.
in the course of a referral. [5199(a)(3)(A)4.]

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)]

5.2. Program Administrator

SUOHC, DPS, and CTRU 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. This person shall have both authority to implement the procedures and the knowledge of infection control principles as they apply specifically to the facility. When the administrator is not on site, there shall be a designated person with full authority to act on his or her behalf. [5199(c)(1)]

5.3. Written Infection Control Procedures

Written Infection Control Procedures shall be available at the worksite and 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)]
  - Guidance on effective disinfectants is available on the EPA webpage at https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
  - Guidance on cleaning and disinfection in healthcare facilities is available at https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/EnvironmentalCleaning.aspx
- Source control procedures.
  Source control procedures minimize the spread of potentially infectious airborne particles and droplets from symptomatic individuals. These procedures shall include the following: [5199(c)(2)]
  - Posting signs near entrances instructing patients to inform healthcare staff if they have symptoms of respiratory infections;
  - Posting information about respiratory hygiene/cough etiquette and making surgical or procedure masks and tissues available to symptomatic patients; http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm. (DPS shall incorporate these recommendations to the extent reasonably practicable.)
  - Making adequate handwashing facilities with soap or alcohol-based hand sanitizers available to patients and people accompanying them;
  - Placing symptomatic persons in a separate room or area, preferably with a separate ventilation system; and
  - Include the method of informing persons with whom employees will have contact of the source control methods.
  - Surgical masks (i.e., with ties) or procedure masks (i.e., with ear loops) should be used for source control, as they greatly decrease the chance of infectious material escaping the mask. N95 respirators with exhalation valves must not be used for source control, as these do not stop the release of particles and droplets.
- Procedures for the screening and referral of cases and suspected cases of Airds 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.
However, if the SUOHC contacts the local health officer and determines that no facility is available to provide airborne infection isolation, then the patient may remain at the employer’s facility. The SUOHC shall continue to contact the local health officer and other facilities every 24 hours to attempt the transfer.

The patient is not required to be transferred if the treating physician determines that the transfer would be detrimental to the patient’s condition. The patient’s condition shall be assessed every 24 hours to determine if they can be safely transferred, and the SUOHC shall document the determination. If a transfer is determined to be safe, it must occur within the timeframes described above.

Sample criteria for screening that may be adopted in nonmedical settings can be found at [http://www.dir.ca.gov/Title8/5199f.html](http://www.dir.ca.gov/Title8/5199f.html)

Patients exhibiting flu symptoms including coughing, other respiratory symptoms, fever, sweating, chills, muscle aches, weakness, and malaise during flu season do not require referral and transfer.

CTRU conducts clinical research on human subjects, so CTRU shall refer the human subjects with suspected ATD symptoms to their primary care health providers or transfer them to a suitable facility for isolation and treatment. The human subjects’ primary care providers or the healthcare facility accepting the patients shall report the AirID cases or suspected cases to the local health officer.

- 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 away from other patients, preferably with a separate ventilation or filtration system, if possible. The ventilation system used for this purpose is not required to include high-efficiency particulate air filtration.
  - Source control measures must also be a part of this procedure.
  - However, if the patient is not compliant with source control measures then employees shall wear N95 respirators when entering the room or area in which the person requiring referral is located. The use of respirator shall be in accordance with the Stanford University Respiratory Protection program.

  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.

- The person performing the test is knowledgeable about the assessment of ventilation systems.
- Stanford EH&S shall document the assessment in writing, describing the results and conclusion. The type of controls described above shall be included in the DPS annual written infection control procedures review.

5.4. Medical Services for Employees [5199(c)(6)]

SUOHC shall provide medical services to Stanford University’s employees as described in section 6 in this document.

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

Training shall be provided to all employees of the “referring employers” as described above so that they may recognize and refer persons who potentially have an airborne infectious disease in a timely manner and take necessary precautions.

The training shall be provided by a knowledgeable person at the time of initial assignment of employees to tasks where occupational exposure to ATD cases could occur 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.

5.6. 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. Changes to procedures must be updated in writing when required. Any deficiencies found shall be corrected. [5199(c)(8)]

5.7. Recordkeeping [5199(c)(9)]

The following records will be maintained in accordance with the Recordkeeping in the section 10 of this publication:
- Training records;
- Vaccination records;
- Documentation of exposure incidents;
- Records of inspection, testing, and maintenance of non-disposable engineering controls.
- Records required by the Stanford University Respiratory Protection program, if employees wear respirators.

6. Medical Services

6.1. General

Medical services are provided by SUOH at no cost to employees with occupational exposure to ATDs, in accordance with applicable public health guidelines, for the type of work setting and diseases they may encounter at work. SUOH will refer personnel to other facilities, as appropriate.

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

LTBI is an infection of the lungs with \(M.\) \(tuberculosis\) bacteria but with no symptoms and no risk of spreading the infection to others. However, approximately 5 to 10% of LTBI patients will develop active and potentially communicable TB disease if untreated.

Assessment for LTBI shall be made available to all personnel with occupational exposure. This includes DPS and SUOH 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)]

Research laboratories where employees do not work with materials reasonably anticipated to contain \(M.\) \(tuberculosis\) are not required to complete the annual TB

Personnel who experience a TB conversion (i.e., conversion from a previous negative result during TB assessment to a current positive result during a TB assessment) shall be referred to a PLHCP knowledgeable about TB for evaluation for active TB and for advice about LTBI treatment. [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:
  o Inform the employee and the local health officer in accordance with Title 17.
  o Consult with the local health officer and inform the employer of any infection control recommendations related to the employee’s activity in the workplace.
  o Provide the employer a written opinion regarding precautionary removal of the employee from work if active disease is suspected (Section 8.7, below).

In the event of a TB conversion, Stanford EH&S shall record the case on the Cal/OSHA Form 300 Log of Work-Related Injuries and Illnesses unless there is clear evidence that the infection was not contracted at work. To record the case, Stanford EH&S shall place a check in the “respiratory condition” column and enter “privacy case” in the space normally used for the employee’s name.

In addition, Stanford EH&S shall investigate the circumstances of the conversion and correct any deficiencies in the procedures, engineering controls, or PPE that were involved. The investigation shall be documented.

6.3. Vaccinations

6.3.1. 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)]

• The CDC updates the list of vaccinations recommended for healthcare workers on their website available at https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html

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)]

If an employee who initially declined a vaccination later decides to accept it while still covered under the standard, the employee shall make their request in writing. Then SUOHC shall make the vaccination available in accordance with subsection [5199(h)(5)(A)] within 10 working days of receiving the
employee’s written request.

If a vaccine is unavailable, SUOHC shall document its efforts to obtain the vaccine in a timely manner and communicate with employees regarding when the vaccine is likely to become available. SUOHC shall also check for the vaccine’s availability at least every 60 calendar days and inform employees when it becomes available.

6.3.2. 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. If the employee later decides to accept the vaccination and it is still flu season, then SUOHC shall provide it within 10 working days of receiving the employee’s written request.

6.3.3. 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 and CTRU employees with occupational exposure.

Each SUOHC and CTRU 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)]

6.3.4. 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)]

6.4. Post-Exposure Medical Evaluation
Procedures for post-exposure medical evaluation are described in Section 7.

6.5. Additional Medical Services
Additional medical services specific to laboratories and animal operations are discussed in Section 4.3.7 of this document.

7. Exposure Incidents to ATPs-L or Reportable ATDs

7.1. 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.

### 7.2 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 r ATPs-L within a timeframe reasonable for the disease\(^5\), but no later than 72 hours after receiving notification.

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.

### 7.3 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.

### 7.4 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)]

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\(^5\) 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-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.
7.5 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)]

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)]

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)]

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

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.

7.7 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)]

7.8 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.

8. Respiratory Protection

The use of respiratory protection shall be consistent with the Stanford University Respiratory Protection Program, available at: https://ehs.stanford.edu/topic/general-workplace-safety/respiratory-protection-program

- Medical evaluation [5199(g)(5)]
  The employer shall provide a medical evaluation, in accordance with Stanford University Respiratory Protection program, to determine the employee’s ability to use a respirator before the employee is fit tested or required to use the respirator.
- Fit testing [5199(g)(6)]
  - The employer shall perform either quantitative or qualitative fit tests in accordance with the Stanford University Respiratory Protection program. The fit test shall be performed on the same size, make, model and style of respirators that the employee will use. When quantitative fit testing is performed, the employer shall not permit an employee to wear a FFR or other half-facepiece respirator, unless a minimum fit factor of 100 is obtained.
  - The employer shall ensure that each employee who is assigned to use a filtering facepiece or other tight-fitting respirator passes a fit test: (1) At the time of initial fitting; (2) When a different size, make, model or style of respirator is used; and (3) At least annually thereafter.
  - The employer shall conduct an additional fit test when the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of changes in the employee’s physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.
  - If, after passing a fit test, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.
- Training [5199(g)(7)]
  The employer shall ensure that each respirator user is provided with initial and annual training in accordance with the Stanford University Respiratory Protection program.
## Recordkeeping

### 9.1 Summary of Recordkeeping Requirements

<table>
<thead>
<tr>
<th>Record</th>
<th>Information that shall be included in the record</th>
<th>Retention Time</th>
<th>Other applicable Title 8 Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of annual ATD or BSP review</td>
<td>• Name of person conducting the review&lt;br&gt;• Date(s) the review was conducted and completed&lt;br&gt;• Name(s) and work area(s) of employees involved&lt;br&gt;• Summary of conclusions</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>Records of exposure incidents</td>
<td>• Date of the exposure incident&lt;br&gt;• Names and any other employee identifiers used in the workplace of employees who were included in the exposure evaluation.&lt;br&gt;• Disease or pathogen to which employees may have been exposed&lt;br&gt;• Name and job title of person performing the evaluation&lt;br&gt;• Identify of any local health officer and/or PLHCP consulted&lt;br&gt;• Date of the evaluation&lt;br&gt;• 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</td>
<td>At least 30 years (as an exposure record)</td>
<td>3204</td>
</tr>
<tr>
<td>Records of unavailability of vaccine</td>
<td>• Name of person who determined the vaccine was not available.&lt;br&gt;• Name and affiliation of person providing the vaccine availability information.&lt;br&gt;• Date of the contact</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>Records of inspection, testing and maintenance of non-disposable engineering controls (e.g., ventilation system, air filtration systems, biosafety cabinets)</td>
<td>• Name(s) and affiliation(s) of person(s) performing the test, inspection, or maintenance&lt;br&gt;• Date&lt;br&gt;• Any significant findings and actions that were taken&lt;br&gt;For airflow testing of vehicles, the following information shall be recorded:&lt;br&gt;• Model and year of manufacture of the vehicle&lt;br&gt;• Partition design&lt;br&gt;• Any significant findings and actions, including whether there was detectable airflow from the passenger compartment to the employee area</td>
<td>5 years</td>
<td></td>
</tr>
</tbody>
</table>
9.2 Additional Records

Additional records required to be kept by animal operations are discussed in Section 4.4 of this document.

9.3 Availability

- All records required to be maintained in section 10, other than the employee medical records shall be made available upon request to the Chief of the Division of Occupational Safety and Health of the Department of Industrial Relations, or his or her designated representative (Chief) and the National Institute for Occupational Safety and Health (NIOSH), and the local health officer for examination and copying.
- Employee training records, the exposure control plan and/or biosafety plan, and records of implementation of the ATD exposure control and biosafety plan, other than medical records containing individually identifiable medical information, shall be made available as employee exposure records in accordance with Section 3204(e)(1) to employees and employee representatives.
- Employee medical records required by this subsection shall be provided upon request to the subject employee, anyone having the written consent of the subject employee, the local health officer, and to the Chief and NIOSH in accordance with Section 3204 of these orders, Access to Employee Exposure and Medical Records, for examination and copying.
9.4 Transfer of Records

Stanford University shall comply with the requirements involving the transfer of employee medical and exposure records that are set forth in Title 8 CCR 3204, Access to Employee Exposure and Medical Records, of these orders.
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)/Varioloa 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 \(b. \text{anthracis} \))
- 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 \(B. \text{spp.}\))
- 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 \(C. \text{psittaci}\) 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 \(C. \text{trachomatis}\))
- Clostridium botulinum (activities with high potential for aerosol or droplet production, large quantities or high concentrations)
- Coccioidioides 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* (sorulating 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 5199 – Aerosol Transmissible Diseases, http://www.dir.ca.gov/title8/5199.html
• 8 CCR 5199.1 – Aerosol Transmissible Diseases – Zoonotic, https://www.dir.ca.gov/title8/5199-1.html
• 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

• Biosafety, https://ehs.stanford.edu/topic/biosafety-biosecurity
• Occupational Health Medical Surveillance Program, https://ehs.stanford.edu/topic/occupational-injury-illness/medical-surveillance
Appendix G – Core ATD Lab Biosafety Plan

Overview

Stanford University Aerosol Transmissible Diseases program (ATD program) has been developed to minimize personnel exposure to aerosol transmissible diseases in accordance with the Cal/OSHA Title 8 CCR 5199 “Aerosol Transmissible Diseases”. Laboratory activities include laboratory operations where researchers 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. A novel or an unknown pathogen is the one capable of causing serious human disease meeting the following criteria:
   • There is credible evidence that the pathogen is transmissible to humans by aerosols; and
   • 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.

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

This Core ATD ATLab Biosafety Plan, supplemented by local lab biosafety plans for specific protocols approved by the Administrative Panel on Biosafety, describe how to eliminate or minimize exposure to materials containing pathogens that may be spread through aerosols and which can cause serious disease. Together these documents meet the requirements for written biosafety plans in Section (f)(4) of the ATD standard. Local plans are kept, along with updates and training records, in a location available for reference by personnel and regulators.

The Stanford University Administrative Panel on Biosafety (APB) includes, as part of its charge and in alignment with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and NIH Guidelines, oversight of issues covered within the Cal/OSHA ATD standard. Additionally, researchers working with biohazardous materials consult the institutional Stanford University Biosafety Manual, and complete general training in biosafety.

Risk Assessment

The Stanford University Biosafety & Biosecurity team, under the direction of the Biosafety Officer, completes risk assessment for each specific research protocol, which is then approved by the APB. Research protocols are maintained in the online eProtocol system. The table below indicates the eProtocol sections that correspond to the BMBL five-step risk assessment method.
<table>
<thead>
<tr>
<th>Risk Assessment Step</th>
<th>eProtocol Section(s)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Identify the laboratory procedure hazards</td>
<td>Protocol Info:  - Methods  - Safety</td>
<td>Procedure hazards identified in local plan</td>
</tr>
<tr>
<td>3 Make a determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment</td>
<td>Protocol Info:  - Methods  - Biohazardous Agents  - Safety  - Risk</td>
<td>Proposed in protocol and approved by APB</td>
</tr>
<tr>
<td>4 Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment</td>
<td>Protocol Personnel Agent Education Acknowledgement</td>
<td>Principal investigator (PI) staff assignment and responsibility for safety equipment</td>
</tr>
<tr>
<td>5 Review the risk assessment with a biosafety professional, subject matter expert, and the IBC</td>
<td>PI Attestation</td>
<td>Via biovisits conducted by Biosafety &amp; Biosecurity and subsequent briefing to APB APB approval</td>
</tr>
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</table>

**Job Classifications with Exposure**

We have determined that some or all of our laboratory members in the following classifications have occupational exposure when performing certain tasks and procedures, which may include any commonly used aerosol-producing laboratory techniques.

- Principal Investigator
- Staff Scientist
- Post-doctoral Research Fellow
- Student (Undergraduate and Graduate) Researcher

Procedures that may be performed by researchers in job classifications with occupational exposure are shown below.

- Centrifugation
- Dissections or necropsy
- Electroporation
- Flow Cytometry
- Mixing, blending, grinding, shaking, sonicating specimens or cultures
- Pipetting
• Pouring, splitting, or decanting liquids
• Splashing infectious material
• Homogenization
• Vortexing
• Transporting specimens/materials throughout the clinical environment (inside and outside of the lab)
• Infection of animals by inhalation
• Infection of animals by gavage
• Trapping or handling wild animals

Specific APB protocols and local lab biosafety plans contain additional details.

**ATP-Ls: Identification in Laboratory and Incoming Materials**

Each APB protocol and local lab biosafety plan identifies the ATPs-L from Appendix D of the standard. APB protocols indicate the methods used to treat all incoming materials containing ATPs-L as containing the virulent or wild-type pathogen pending verification that the pathogen has been deactivated or attenuated. The APB protocol describes the procedures and communications methods to ascertain the status of incoming materials.

**Exposure Control Measures**

We have established biosafety exposure control measures to protect our researchers from exposure to these ATPs-L, including engineering controls. For any health or safety hazard, engineering controls are always an important method of mitigating the hazard. At our institution, we typically use biosafety cabinets, centrifuge cups and covers, sharps protection systems, and other means to minimize exposure to infectious or potentially infectious laboratory aerosols. The *Stanford University Biosafety Manual* contains detailed guidance on engineering controls selection and use.

**Safe Handling Procedures and Prohibited Practices**

1. Personnel **wash their hands** frequently while working with biohazardous agents, and immediately after removing gloves.
2. **Sniffing or smelling** of cultures is strictly prohibited.
3. **Mouth pipetting** or mouth suctioning is strictly prohibited.
4. **Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses** are prohibited in work areas. Researchers refrain from placing objects (pen, pencil, pipette, etc.) into their mouths while working in the laboratory.
5. **Food and drink are not stored** in refrigerators, freezers, shelves, cabinets, bench tops, ovens, or microwaves where lab materials are present.
6. **Used needles and other sharps** are not sheared, bent, broken, recapped, or re-sheathed by hand. Used needles are not removed from disposable syringes. Contaminated sharps are placed immediately in a puncture-resistant and labeled sharps container.
7. **Leak-resistant containers** are used during the collection, handling, processing, storage, transport, or shipping of aerosol transmissible disease pathogens. The containers are appropriately labeled or color-coded and are closed prior to transport. If outside contamination could occur, the primary container is placed in a second container, which prevents leakage.
8. **Biological safety cabinets (BSC's)** are checked for proper functioning each time they are used. The biosafety cabinet must be certified annually, and the inspection record posted on the biosafety cabinet.
9. **Vacuum lines** are protected with liquid disinfectant traps and HEPA filters. The filters are routinely checked monthly and maintained or replaced as needed.

**Decontamination and Disinfection Procedures**

Researchers may be at risk of infection when coming into contact with surfaces contaminated with ATPs-L. To reduce this risk, we decontaminate and disinfect laboratory surfaces and equipment using procedures outlined in the *Biosafety Manual*, with EPA-registered cleaner(s) or disinfectant(s) listed in eProtocol, in the Protocol Info, Methods section. Decontamination and disinfection are done regularly by lab researchers who perform in-lab procedures, usually at the end of each work shift and after any spill or unplanned release of biohazardous materials.

**Personal Protective Equipment and Respiratory Protection**

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. PPE selections are documented via Stanford’s PPE Assessment process, and in APB protocols. General practices include:

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

Researchers who are required to wear respirators are covered under our written Respiratory Protection Program, in accordance with title 8 sections 5199 and 5144. We provide our researchers 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 researchers 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 researchers 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.

Emergency procedures for uncontrolled releases inside or outside the laboratory facility are outlined in the Biosafety Manual. Researchers contact EH&S at call (650) 725-9999 for assistance and notification.

Generally, emergency PPE is stored inside laboratories as needed, and at EH&S for responders. Additional supplies and equipment to be used in emergency response involving ATPs-L, particularly for BSL-3 laboratories, are specified in APB protocols.

Stanford EH&S reports release incidents to the appropriate local health officer, outside agencies, and regulators as required by applicable regulations, including those promulgated by Santa Clara County and the city of Palo Alto.

**Medical Services**
Medical services are provided to researchers with exposure to ATPs-L to prevent and treat lab-acquired infections (LAIs), and also after exposure incidents. Medical services are provided by the Stanford University Occupational Health Center (OHC) at 484 Oak Road, Stanford CA 94305.

**Tuberculosis Surveillance Program**
- Laboratory researchers who work with *M. Tuberculosis* are enrolled in the TB surveillance program.
- TB assessment tests are offered initially and every six months.
- Researchers who experience a TB conversion are evaluated by an OHC physician and provided latent TB infection treatment.

**Vaccinations**
- Vaccines applicable to ATPs-L occupational exposures are provided by the Occupational Health Center.

**Incident Reporting and Medical Exposure Follow-up**

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. 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 researcher requires further evaluation by a physician or other licensed health care provider (PLHCP).

In the event of an exposure incident (laboratory), OHC provides medical services to laboratory researchers who were exposed to the ATPs-L. The EH&S Biosafety Officer or designee shall conduct an incident investigation as described in the SU ATD Plan Section 7 “Exposure Incidents to ATPs-L”.

The laboratory researcher must complete the following actions following the occupational ATPs-L exposure:
- Inform supervisor.
- Call Occupational Health Center for evaluation: (650) 725-5308 if event involves a work-related injury or illness. For after-hours EH&S emergencies, call (650) 725-9999
- Complete an SU-17.

**Communication of Hazards and Researcher Training**

We provide training to our researchers who have occupational exposure to ATP-L, as listed at the beginning of this biosafety plan. This training will be provided to each researcher 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.

The ATD standard training is provided online by EH&S. All required topics are covered and all interactive questions shall be answered within one business day by an EH&S person knowledgeable in the subject matter as it relates to our workplace, and who is also knowledgeable in our laboratory ATD exposure control plan. EH&S Biosafety Officer contact is below:

Ellyn Segal, PhD
Obtaining Active Involvement of Researchers 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 researchers, not just managers and supervisors. Active involvement means more than merely having a form available that researchers can fill out at their leisure.

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

- Interactive questions and answers during trainings
- Discussions regarding risks and control measures during biovisits and laboratory visits, including risk assessments for APB protocols
- Discussions with PIs during incident investigations including SU-17 follow-up
- Lab safety coordinator meetings and discussions

Review of Plans for Facility Design and Construction

The EH&S Biosafety Officer or designee reviews the plans for new facility design and construction prior to the start of the work if it may affect the control measures for ATPs-L. This allows 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 is also done for moves into new laboratory facilities. We coordinate with members of the Stanford Department of Project Management (DPM) who oversee construction projects, and the department of Land, Buildings, and Real Estate (LBRE) to complete project reviews. Stanford has also established requirements for facility design and construction that are documented in our Laboratory Standard & Design Guide.

Inspection of Laboratory Facilities

Regular inspections of our laboratory facilities are performed so that hazards may be found and corrected in a timely manner. Our inspections include an annual audit of our biosafety procedures as well as a physical inspection of a representative sample of facilities and equipment. Additionally, lab groups are encouraged to conduct their own periodic inspections of facilities and equipment. All uses of biological safety cabinets must first include a visual inspection to ensure that the equipment is certified and functioning properly. Laboratory inspections records are kept for five years.

For new APB protocols, members of the Biosafety & Biosecurity team, who are experienced with biosafety inspections, conduct biovisits as part of the risk assessment and protocol approval process, using the biosafety laboratory inspection checklist below. Results are documented by the team and shared with the PI for corrective action, then subsequently reviewed by the APB. Hazards are corrected by following the procedures in our Injury and Illness Prevention Program for hazard correction, including correcting imminent hazards immediately, if possible.
Biosafety Laboratory Inspection Checklist

Name and Job Title of the personnel* conducting inspection:
______________________________________________________________________________

PI_________________________________    Date______________________________________

Building and Room ______________________________________________________________

APB # _________________________________________________________________________

Agents ________________________________________________________________________

General Checklist
☐ Equipment/logistics
☐ PPE
☐ Door placard/signage
☐ Universal Precautions
☐ Safety Sharps
☐ Waste Disposal;
☐ BSC use/certification
☐ Autoclave use
☐ Shared spaces
☐ Transportation
☐ eProt Process

Research Specifics
☐ Tier III Training
☐ Use of Animals
☐ Sharing materials
☐ Exposures/Incidents

Occupational Health
☐ BBP (Part I)
☐ BBP – ECP (Part II)
☐ ATD
☐ AEA Form
☐ LAOHP
☐ Medical Surveillance
☐ Health Immune Status
☐ Vaccinations
☐ Titers
☐ Respirator Requirements

Comments:

*EH&S Biosafety & Biosecurity staff and/or lab member
This local ATD lab biosafety plan supplements the Stanford University Core ATD Lab Biosafety Plan.

Please complete each section as indicated.

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<thead>
<tr>
<th>Principal Investigator/Supervisor:</th>
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Local ATPs-L

The pathogens below appear in Appendix D of the ATD standard and trigger coverage. Several may be exempt, based on certain characteristics (e.g., only clinical samples containing adenovirus trigger coverage). See Appendix D for complete details, or contact EH&S Biosafety & Biosecurity.

*Check the ATPs-L below associated with the APB protocol and any others either present or reasonably expected to be present in laboratory materials.*

- Adenovirus
- Arboviruses
- Arenaviruses
- Bacillus anthracis
- Blastomyces dermatitidis
- Bordetella pertussis
- Brucella abortus
- Brucella canis
- Brucella maris
- Brucella melitensis
- Brucella suis
- Burkholderia mallei
- Burkholderia pseudomallei
- Chlamydia pneumoniae
- Chlamydia psittaci
- Chlamydia trachomatis
- Clostridium botulinum
- Coccidioides immitis
- Coccidioides posadasii
- Corynebacterium diphtheriae
- Coxiella burnetti
- Crimean-Congo haemorrhagic fever virus
- Cytomegalovirus (human)
- Eastern equine encephalomyelitis virus
- Ebola virus
- Epstein-Barr virus
- Escherichia coli (shiga toxin producing)
- Flexal virus
- Francisella tularensis
- Guanarito virus
- Haemophilus influenzae
- Hantaviruses
- Helicobacter pylori
- Hemorrhagic fever viruses
- Hendra virus
- Hepatitis B Virus
- Hepatitis C Virus
- Hepatitis D virus
- Histoplasma capsulatum
- Human Herpesvirus 6A
- Human Herpesvirus 6B
- Human Herpesvirus 7
- Human Herpesvirus 8
- Influenza Viruses
- Junin virus
- Kyasanur forest disease virus
- Lassa fever virus
- Legionella pneumophila
- Lymphocytic Choriomeningitis Virus
- Machupo virus
- Measles Virus
- Monkeypox virus
- Mumps Virus
- Mycobacterium tuberculosis complex7
- Mycobacterium species
- Mycoplasma pneumoniae
- Neisseria gonorrhoeae
- Neisseria meningitides
- Nipah virus
- Omsk hemorrhagic fever virus
- Parvovirus B19
- Prions
- Rabies virus
- Retroviruses
- Rickettsia akari
- Rickettsia australis
- Rickettsia conorii
- Rickettsia japonicum
- Rickettsia prowazekii
- Rickettsia rickettsii
- Rickettsia siberica
- Rickettsia typhi
- Rickettsia tsutsuagmushi
- Salmonella species
- Salmonella typhi
- SARS coronavirus
- Shigella species
- Streptococcus species, group A
- Tick-borne encephalitis
- Viruses11
- Vaccinia Virus
- Varicella-Zoster Virus
- Variola major (Smallpox virus)
- Variola minor (Alastrim)
- Venezuelan equine encephalitis virus
- West Nile Virus
- Western equine encephalitis virus
- Yersinia pestis
- Other novel or unknown pathogen (Specify:)

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RS #20-06 Revision Date 08/21/2020
Attach and review Infectious Pathogen Safety Data Sheets prior to conducting any work with the pathogens indicated above:


Select the aerosol producing procedures used in this protocol:

- Centrifugation
- Dissections or necropsy
- Electroporation
- Flow cytometry
- Mixing, blending, grinding, shaking, sonicating specimens or cultures
- Pipetting
- Pouring, splitting, or decanting liquids
- Splashing infectious material
- Homogenization
- Vortexing
- Transporting specimens/materials throughout the clinical environment (inside and outside of the lab)
- Infection of animals by inhalation
- Infection of animals by gavage
- Trapping or handling wild animals
- Other:

Indicate selected biosafety level based on risk assessment:

- BSL2
- BSL2+
- BSL3

List additional safety measures beyond standard containment and microbiological practices for the selected biosafety level, such as special equipment, PPE, handling practices, decontamination procedures:

Indicate any other biosafety risk management practices, including additional inspections and training, for this protocol:
Biosafety Laboratory Inspection Checklist

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_______________________________________________________________________________
PI_________________________________    Date_______________________________________

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Comments:

*EH&S Biosafety & Biosecurity staff and/or lab member