Department of Environmental Health
Occupational Health Program

- Occupational Health Surveys
  - Employee Training
  - Respiratory Protection
  - Asbestos and Lead Management
  - Indoor Air Quality Evaluations
  - Ventilation System Evaluation
  - Hearing Conservation
  - Ergonomic Consultations
Department of Environmental Health
Occupational Health Program

- **Biological Hazard Consultation**
  - *Injury Illness Prevention Reviews*
  - *Hazard Communication*
  - *Environmental Compliance Assistance*
  - *Childhood Lead Poisoning Investigations*
  - *Consultation with Other Governmental Agencies*
  - *Public Information*
Biosafety Definitions

- **Biosafety**: The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated. Webster’s Medical Dictionary

- **Biosafety**: the collection of handling and containment procedures, guidelines, and precautions that protect humans and the environment from exposure to biohazardous agents or materials. UC Davis Safety Services
Zoonotic Biosafety for Vector Surveillance & Control Programs

- Zoonotic aerosol transmissible disease (ZATD) Program Requirements: Cal/OSHA T8 CCR 5199.1 [http://www.dir.ca.gov/title8/5199-1.html](http://www.dir.ca.gov/title8/5199-1.html)

- ZATD is a disease that is transmissible from animals to humans and is caused by a zoonotic aerosol transmissible pathogen (ZATP). ZATPs include pathogens that are classified as transmissible by either droplets or airborne route.

- Effective August 5, 2009
Cal/OSHA Definitions

- **Aerosol transmissible pathogen (ATP).** A pathogen that is transmitted by liquid or solid particles in the air, including droplets, droplet nuclei, fomites and dusts.

- **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.
Cal/OSHA Definitions

- **Occupational exposure.** 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.
How are Zoonotic Diseases Transmitted?

- Vector Borne
- Animal Bites
- Contaminated Sharps
- Direct Contact (No Aerosol Intermediary)
- Oral (Direct or Hand to Mouth)

**Aerosol**
- Inhalable Particle
- Air Droplets to Skin, Eyes, M.M., Mouth
- Surface Contamination from Air Droplets Transferred to Skin, Eyes, M.M., Mouth
Pathogens Classified as ZATD?

- No list of ZATPs, in Cal/OSHA regulations.
- Instead of a list, employer is to use their knowledge and rely on the sentinel activities of the local health agencies, California Department of Fish and Game (CDFG), California Department of Food and Agriculture (CDFA), California Department of Public Health (CDPH), US Department of Agriculture (USDA), Centers for Disease Control (CDC), etc.
Other References for Determining ZATPs

- Iowa State University
  http://www.cfsph.iastate.edu/Zoonoses/zoonotic-disease-resources.php

- State Veterinarian’s Office
  http://www.cdfa.ca.gov/ahfss/Animal_Health/Disease.html

- University of California, Davis

- What ZATP’s do You Work With?
Scope of Regulation

5199.1 – Zoonotic Aerosol Transmissible Diseases (ZATDs)
Scope and Applicability

Ensure that the Injury Illness Prevention Program (IIPP) includes specific procedures for ZATP hazards
Injury and Illness Prevention Program (IIPP)

- Cal/OSHA T8CCR 3203 [http://www.dir.ca.gov/title8/3203.html](http://www.dir.ca.gov/title8/3203.html)

- General Cal/OSHA requirement to:
  - Identify hazards unique to each employee’s job
  - System for safety compliance (including training)
  - System for correcting unsafe/unhealthy conditions
  - Recordkeeping requirements
Biosafety IIPP Components

- Specifically for ZATPs, the IIPP must include:
  - Hazard reduction methods
  - Sanitation
  - Training
  - Investigation of exposures
  - Personal protective equipment (PPE), where applicable
  - Biosecurity, where applicable

- Must use general IIPP process for zoonotic diseases that are not transmitted by infectious aerosols
Application
Graduated Approach

- Certain work settings (capturing / sampling wildlife to detect infection with ZATPs, laboratories, culling operations, and vertebrate animal research facilities) have increased requirements above and beyond the IIPP.

- All other operations within the scope have increased requirements only based on heightened risk as determined by:
  - An alert issued by the Local Health Officer, CDC, CDFA, CDFG, CDPH, USDA or USDOI (applicable to the area/species)
  - A quarantine order, movement restriction or other infection control order by the USDA or CDFA
5199.1 – Zoonotic Aerosol Transmissible Diseases (ZATDs)
Scope and Applicability

Management, capture, sampling, transportation or disposal of wild birds or other wildlife
Farms producing animals or animal products
Slaughterhouses and initial processing facilities for untreated animal products, byproducts, or wastes
Veterinary, animal inspection, and other animal health operations
Importers of live animals and untreated animal products
Zoos, animal parks, pet stores and other operations in which animals are displayed, transported, or housed
Laboratory operations involving samples, cultures, or other materials potentially containing zoonotic aerosol transmissible pathogens (ZATPs)

ZATD incident response

Ensure that the Injury Illness Prevention Program (IIPP) includes specific ZATP hazards

ADDITIONAL REQUIREMENTS

- Capturing or sampling wildlife to determine whether they are infected with ZATPs
- Collecting and disposing of wildlife for which an alert regarding the potential of zoonotic infection has been issued
- Operations for which the United States Department of Agriculture (USDA) or California Department of Food and Agriculture (CDFA) have issued a quarantine order, movement restriction, or other infection control order due to an increased risk of ZATP infection
- Handling, culling, transporting, killing, eradicating, or disposing of animals infected with ZATPs
- Cleaning or disinfecting areas used, or previously used, to contain such animals or their wastes.
- Laboratory operations involving samples, cultures, or other materials potentially containing ZATPs
- Vertebrate Animal Research Facilities
Flow Diagram of ZATD Regulation

Management, capture, sampling, transportation or disposal of wild birds or other wildlife
Farms producing animals or animal products
Slaughterhouses and initial processing facilities for untreated animal products, byproducts, or wastes
Veterinary, animal inspection, and other animal health operations
Importers of live animals and untreated animal products
Zoos, animal parks, pet stores and other operations in which animals are displayed, transported, or housed
Laboratory operations involving samples, cultures, or other materials potentially containing zoonotic aerosol transmissible pathogens (ZATPs)

Ensure that the Injury Illness Prevention Program (IIPP) includes specific ZATP hazards

- Capturing or sampling wildlife to determine whether they are infected with ZATPs
- Collecting and disposing of wildlife for which an alert regarding the potential of zoonotic
- Operations for which the United States Department of Agriculture (USDA) or California Department of Food and Agriculture (CDFA) have issued a quarantine order, movement restriction, or other infection control order due to an increased risk of ZATP infection
- Handling, culling, transporting, killing, eradicating, or disposing of animals infected with ZATPs Cleaning or disinfecting areas used, or previously used, to contain such animals or their wastes.
- Laboratory operations involving samples, cultures, or other materials potentially containing ZATPs

Comply with 5199.1(b) and (e)

- Written procedures
- Work procedures
- PPE
- Cleaning and decontamination
- Medical services (according to recommendations)
- Training
- Required respirator use in certain cases
- Maintain records (e.g., hazard identification, exposure records, medical records, etc.)

Comply with 5199.1(c) and (e)

- Written procedures
- Identify restricted areas, post signs Supervised entry
- Respiratory protection requirements Sanitary facilities including change rooms and showers Medical services (surveillance, vaccination, prophylaxis, etc.) Training (topics specified) Record of entry
- Maintain records (e.g., hazard identification, exposure records, medical records, etc.)

Comply with 5199.1(d)

- Written procedures
- Detailed work plan Job tasks with occupational exposures Control measures (engineering controls, work practices, etc.) Access to water and sanitation /decontamination facilities Heat illness prevention Supervised entry
- Respiratory protection requirements Procedures for toxic gas application Disposal, decontamination Medical services (vaccination, surveillance, follow-up, etc.) Training (topics specified) Maintain records (e.g., hazard identification, exposure records, medical records, etc.)

Comply with 5199(f)

Lab is operated in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition
I. Designation of a biological safety office II. BSO
III. Establishment of ATP Biosafety Plan IV. List of ZATPs expected at facility V. Risk assessment by the BSO for the expected ZATPs and activities VI. Job classifications / tasks with occupational exposure VII. Safe handling procedures VIII. Engineering controls IX. Disinfection / decontamination procedures X. Personal protective equipment (PPE) XI. Respiratory protection XII. Emergency procedures for uncontrolled releases XIII. Employee medical services (vaccinations, latent tuberculosis infection surveillance, exposure incident follow-up)
XIV. Employee training (includes specific topics, initial and annual)
XV. Active involvement of employees in reviewing the Biosafety Plan
XVI. BSO review of facility design and construction
XVII. Inspection of lab and audit of procedures at least annually
XVIII. Recordkeeping

Comply with 5199.1(e) and "Biosafety in Microbiological and Biomedical Laboratories" (BMBL), 5th edition and if Animal Biosafety Level 3 or above, also comply with 5199.1(d)
Capture/Sample Wildlife Group

- Capturing or sampling wildlife to determine whether they are infected with ZATPs
- Collecting and disposing of wildlife for which an alert regarding the potential of zoonotic infection has been issued

Comply with 5199.1(b) and (e)

- Written procedures
  - Work procedures
  - PPE
  - Cleaning and decontamination
  - Medical services (according to recommendations)
  - Training
- Required respirator use in certain cases
- Maintain records (e.g., hazard identification, exposure records, medical records, etc.)
Laboratory operations involving samples, cultures, or other materials potentially containing ZATPs

Comply with Title 42

Lab is operated in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition

I. Designation of a biological safety officer (BSO)
II. Establishment of ATP Biosafety Plan
III. List of ZATPs expected at facility
IV. Risk assessment by the BSO for the expected ZATPs and activities
V. Job classifications / tasks with occupational exposure
VI. Safe handling procedures
VII. Engineering controls
VIII. Decontamination / disinfection procedures
IX. Personal protective equipment (PPE)
X. Respiratory protection
XI. Emergency procedures for uncontrolled releases
XII. Employee medical services (vaccinations, latent tuberculosis infection surveillance, exposure incident follow-up)
XIII. Employee training (includes specific topics, initial and annual)
XIV. Active involvement of employees in reviewing the Biosafety Plan
XV. BSO review of facility design and construction
XVI. Inspection of lab and audit of procedures at least annually
XVII. Recordkeeping
Lab Biosafety Programs

Reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents. Biosafety is achieved by implementing various degrees of laboratory control and containment, through laboratory design and access restrictions, personnel expertise and training, use of containment equipment, and safe methods of managing infectious materials in a laboratory setting.

Biosafety in Microbiological and Biomedical Laboratories
ZATP Lab Biosafety Program

- Designation of a biological safety officer (BSO)
- Establishment of ZATP Biosafety Plan
- List of ZATPs expected at facility
- Risk assessment by the BSO for the expected ZATPs and activities
- Job classifications / tasks with occupational exposure
- Safe handling procedures
BMBL establishes ascending levels of containment that correspond to risks associated with handling infectious microorganisms that present similar hazardous characteristics. Biosafety Level 1 lowest risk. Biosafety Level 4 highest risk.

The primary risk criteria used to define the four ascending levels of containment, referred to as biosafety levels 1 through 4, are infectivity, severity of disease, transmissibility, and the nature of the work being conducted.
Lab Biosafety Level Criteria

Recommendations are given under 4 major headings for each Biosafety Level:

- Standard Microbiological Practices
- Special Practices
- Safety Equipment Primary Barriers & PPE
- Laboratory Facilities (Secondary Barriers)
Lab Biosafety Levels

Biosafety Level 1

- Work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.
- Represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing.
Lab Biosafety Levels

Biosafety Level 2

- Work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.
- Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials.
Lab Biosafety Levels

- **Biosafety Level 2**
  - While BSL-2 organisms are not typically known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups.
  - Secondary barriers, such as hand washing sinks and waste decontamination facilities, must be available to reduce potential environmental contamination.
Biosafety Level 3

- Work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.

- More emphasis on barriers for protection; laboratory manipulations should be performed in a BSC or other enclosed equipment, such as a gas-tight aerosol generation chamber, and restricted lab access.
Biosafety Level 4

- Work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.
- Work in a Class III BSC or in a full-body, air-supplied positive-pressure personnel suit, the BSL-4 facility is isolated, with specialized ventilation and waste requirements.
Ventilation Engineering Controls

Consistent with Cal/OSHA & BMBL 5th Edition

• General Ventilation Requirements
  • Collect and remove contaminants out of building away from air intakes and environmental receptors
  • Ventilation rate tested annually
  • Laminar Flow desirable

• Local Exhaust Ventilation Requirements
  • Chemical fume hoods CCR 5154.1
  • Biological Safety Cabinets (BSC’s) CCR 5154.2
BSL-3 General Ventilation Requirements

- Ducted Ventilation System
- Lab Exhaust Air not Recirculated
- Exhaust Air Away from Air Intakes or Occupied Areas (or HEPA Filtered)
- Directional Airflow (from Clean to Dirty)
- Flow cannot Reverse under Power Failure
- Directional Airflow Indicator Device Must be Present at lab Entrance
Directional Airflow Criteria

- Important Ventilation Design Criteria:
- Number of Barriers (doors/rooms) as you move into lab
- Negative Pressurization (cascade)
  - Amount of negative pressurization
  - Leakage
- Air Changes per Hour (ACH)
  - Amount of ACH
Directional Airflow Criteria

- For BSL-3 Labs BMBL does not specify amount of negative pressure or ACH needed.

- National Institutes of Health (NIH) criteria:
  - 0.05” WG negative pressure at each barrier door and lab. Minimum 6 ACH

- TB Control in Health Care criteria:
  - 0.01” WG negative pressure in isolation room. Discusses leakage issue. Minimum 12 ACH. Clearance times; no respirator
Local Exhaust Ventilation Requirements

- **Biological Safety Cabinets (BSC’s)**
  - Three BSC classes (I, II, III)
  - Used for primary containment of lab procedures that cause material aerosolization
  - Installed away from airflow disruptions in lab
  - Not used for heavy chemical exposure control
  - Minimum face velocity requirements (checked annually)
  - Can recirculate air from BSC to lab if has HEPA filter (BSC must be certified annually)
Biological Safety Cabinets (BSC’s)

- **Class I BSC**
  - Personal & environmental protection. Can be used for biosafety levels 1-3 depending on risk assessment

- **Class II BSC**
  - Personal, product, & environmental protection. Can be used for biosafety levels 1-3 depending on risk assessment. (Types A1, A2, B1, & B2)

- **Class III BSC**
  - Personal, product, & environmental protection. Can be used for biosafety levels 1-4 depending on risk assessment
ZATP Lab Biosafety Program

- Decontamination / disinfection procedures
- Personal protective equipment (PPE)
- Respiratory protection
- Emergency procedures for uncontrolled releases
- Employee medical services (vaccinations, latent tuberculosis infection surveillance, exposure incident follow-up)
ZATP Lab Biosafety Program

- Employee training (includes specific topics, initial and annual)
- Active involvement of employees in reviewing the Biosafety Plan
- BSO review of facility design and construction
- Inspection of lab and audit of procedures at least annually
- Recordkeeping
Thank You!

Questions