Section 2 - Biosafety and Containment

Background and Introduction

Purpose and scope

This section of the Laboratory and Research Safety Manual serves as a general biosafety and containment manual for UC ANR research operations. This section of the manual is based on best practices identified in, among others sources, the CDC publication *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*, guidelines published by the U.S. Department of Agriculture - Animal Plant Health Inspection Service (USDA-APHIS), and guidelines published by National Institutes of Health - Office of Biotechnology Activities (NIH OBA). In addition to guidelines published by federal agencies, guidance in this manual is intended to support compliance with the California Medical Waste Management Act, the California Aerosol-Transmissible Disease Standard (8CCR5199), Zoonotic Disease Standard (8CCR5199.1), and Bloodborne Pathogen Standard (8CCR5193)

Biosafety is defined as, "The discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials" (CDC, BMBL 5th ed.)

The term "biological materials" refers to living organisms or biologically active molecules, and may include any of the following:

- Recombinant or synthetic DNA/RNA (plasmids, cloned materials, siRNA, and experimentally-produced viral vectors)
- Genetically-modified organisms (animals, microorganisms, plants, insects, cells/cell lines)
- Human products, including blood, tissues, bodily fluids, clinical specimens
- Live animals, carcasses, or animal products including tissues, cells, blood, or other bodily fluids
- Pathogenic microorganisms (including human, animal, or plant pathogens)
- Arthropod plant pests and disease vectors
- Plants, animals, insects, microorganisms, or cells that produce toxic compounds
- Select Agent organisms (including the toxins they produce)

These biological materials may pose health risks to animals or plants. When the risk posed to animals or plants is high enough to warrant human health protection measures or other containment precautions to prevent release, then these biological materials may be considered hazardous biological agents or biohazards.

"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." (CDC, BMBL 5th ed.)

Biological Risk Assessment

The foundation of biological safety practice is the biological risk assessment. Due to the variety of practices, pathogens, and species that may be involved in biological research operations, the process for assessing risk is usually a case-by-case determination based upon established standards in biological safety. In general the factors to be considered in a biological risk assessment are:

- The inherent risk posed by the biological materials or agent
- Any additional risks posed by the experimental procedures, handling, or storage
- Containment or confinement features of the facilities where the work is conducted
- Competency and level of training in employees who handle the materials

A biosafety plan template is included as an appendix to this safety manual. The biosafety plan is designed to guide the user in conducting and documenting a biological risk assessment for hazardous or regulated biological materials. Once a risk assessment has been documented for the work, then safety controls can be applied to the risk that have been identified. The safety controls which are selected for use should also be captured in the biosafety plan

Classes of biological hazards and regulated materials

Microorganisms such as viruses, bacteria and fungi biological hazards are classified into four categories called Risk Groups, according to their level of relative risk to human health. ***Important compliance requirements and restrictions associated with specific materials or research activities are presented in bold red italics.***

Risk group one (RG1) organisms are those which are not known to cause disease in health adult humans. Risk group one agents may still cause serious disease in immunocompromised people, children, elderly adults, non-human animals, or plants.

Risk group two (RG2) organisms are known to cause disease in humans, but the disease is usually not severe or is treatable or preventable with medical interventions. Examples of this type of microorganism are pathogenic *E. coli* strains, *Salmonella* species, *Aspergillus* species, and *Francisella tularensis*. ***Any storage, use, or research on risk group two agents or biological materials that require Biosafety Level 2 or higher level of protection is prohibited at ANR facilities unless the principal investigator first obtains approval from a campus Institutional Biosafety Committee (IBC).*** If campus IBC review does not appear to be appropriate, contact UC ANR office of Environmental Health & Safety for further instruction before use of biological materials requiring protection of Biosafety Level 2 or higher.

Risk group three (RG3) organisms are those known to cause serious or lethal disease in humans. The disease may have some treatment or prevention options. Many risk group three agents are also infectious via aerosol, causing disease if they become airborne and employees are exposed to the contaminated air. Examples of risk group three agents are *Brucella abortus*, *Burkholderia mallei*, and *Coxiella burnettii*. Risk group four (RG4) organisms cause serious or lethal disease and medical interventions are usually not available or effective. An example of this type of organism is Ebola virus. **Possession or deliberate culture of risk group three and risk group four agents is prohibited in ANR facilities. If any risk group three and risk group four agents are ever found or identified at an ANR facility, the party in possession of the materials must secure them from any possible access by others and immediately contact EH&S for further instructions.**

Select Agent pathogens and toxins – certain biological agents and toxins produced by biological agents have been identified by the U.S. government as having great potential for deliberate or malicious misuse. Any possession of these materials (even accidental or unintentional) is highly regulated and controlled by U.S government agencies. A list of Select Agents and Toxins is included as an appendix to this manual. **Any storage or use of Select Agents or Toxins at ANR facilities is prohibited (see appendices for list of Select Agent Pathogens and Toxins). If any Select Agents or Toxins are ever found or identified at an ANR facility, the party**

in possession of the materials must secure them from any possible access by others and immediately contact EH&S for further instructions. Contact EH&S for any questions or concerns related to Select Agent Pathogens.

Plants and animals are not assigned to risk groups. However, sometimes materials are considered to have the same risk as a specific pathogen if the pathogen may be present in the materials. These materials may be called "other potentially infectious materials" or OPIM. Some examples of OPIM are: mammalian cells used in tissue culture, animal tissue samples, carcasses of animal species that are known to harbor zoonotic disease, and bedding and waste from animal housing or husbandry operations. Plant materials and soils may also harbor pathogenic microorganisms that could present exposure hazards if aerosolized. In addition to infectious diseases, microorganisms and airborne debris from plants or animals research can cause hazardous allergic or asthmatic conditions in healthy adults. These serious health conditions are a result of the human immune system reacting to exposures to airborne materials which are not generally considered pathogens (grain dusts, soils, ground up plant materials).

Bloodborne pathogens in the broadest sense can refer to pathogenic organisms that reside in blood or are transmitted through contact with blood. However, Cal/OSHA bloodborne pathogen regulations (8CCR5193) and mandated safety controls are primarily applicable to work-related exposures to human blood, human tissues, and other potentially infectious materials commonly encountered in medical settings. Pathogen exposures that occur due to exposure to animals or their waste materials are considered zoonotic pathogen exposures. These pathogens (described below) are covered under different regulations. ***Research activities that involve collection or handling of human blood, tissues, or body fluids must be reviewed and approved by (or receive written confirmation of exemption from) an Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) at a UC campus.***

Zoonotic pathogens are pathogenic agents which can cause disease in humans and come from animal sources. The infected animals may show no signs of disease, but the disease they harbor may cause serious illness in human who are exposed. Exposure to zoonotic disease is a significant occupational hazard for employees who work with or around animals (alive or dead), their housing/bedding, or untreated waste from animal operations. Water and airborne dust coming from animal operations may also pose threat to human health. ***A written safety plan as specific in the Cal/OSHA zoonotic disease standard (8CCR5199.1), is required for any research involving potential exposure to zoonotic disease agents. This requirement may be fulfilled by an IBC-approved BUA or other project-specific documentation (IACUC protocol)***

Pathogens affecting only non-human animals – some pathogens may affect animals only and may not cause disease in humans. Protective measures are important in work with animals so that infectious diseases are not transferred in and among research or wild animal populations by human activities. Research involving potential for exposure to, or transmission of, animal diseases may require specific permits from California Department of Fish and Game (CDFG), California Department of Food and Agriculture (CDFA), and/or US Department of Agriculture Animal Plant Health Inspection Service (USDA-APHIS). ***Research activities involving any organisms regulated under CDFG, CDFA, or USDA-APHIS permits should be reported to EH&S, ideally with a copy of the permit provided for compliance review and recordkeeping. Research activities involving animal pathogens that are regulated by CDFA or USDA-APHIS may require review and approval from a campus Institutional Biosafety Committee (IBC).***

Quarantined and regulated pests (QARP) is a term applied to plant pests that may cause serious or detrimental effects to local ecology, agriculture, or the environment. Quarantined and regulated pests, can be microorganisms, invertebrates, or other plants. These pests are identified at a local level by the county agricultural commissioner (CAC), at the state level by California Department of Food and Agriculture (CDFA), and at the federal level by US Department of Agriculture Animal Plant Health Inspection Service (USDA-APHIS). Movement of plant-associated invertebrates, plant materials, soils, or OPIM across county lines, into or out of quarantine zones, across state lines inside the U.S., importation into U.S., or exportation to other countries may require specific authorization from local, state, or federal regulatory authorities. ***Research activities involving any organisms regulated under CDFG, CDFA or USDA-APHIS permits should be reported to EH&S, ideally with a copy of the permit provided for compliance review and recordkeeping. Research activities involving microbial plant pathogens that are regulated by CDFA or USDA-APHIS may require review and approval from a campus Institutional Biosafety Committee (IBC).***

Routes of exposure

Each pathogen has one or more ways to infect and cause disease in the desired host. These are called routes of exposure. If we understand a pathogen's route of exposure, then we have a better chance of preventing a disease-causing exposure event.

In protecting human health, we focus on the routes that a human worker may be exposed to a pathogen. That is, we look for the route by which the pathogenic organism may gain access to the human body in order to cause disease. Those routes, in order of importance are:

- Inhalation (of airborne contaminants)
- Ingestion (including direct contact with mouth/eyes/nose)
- Wound/blood contact

A key exposure control for biological hazards is to minimize aerosol-generating activities and to be mindful of the airborne contamination that such activities can generate. Beyond the immediate danger of inhalation, settled aerosols can lead to surface contamination of workspaces and establishment of a reservoir of contamination in a lab or work area. Whenever energy is added to a biological sample, the production of aerosols and resulting contamination must be considered and mitigated with proper use of protective equipment and sanitation of work areas. Examples of aerosol-generating activities are: mixing, grinding, cutting, sweeping, and applying pressurized air or water to a sample. The actions of natural wind or ventilation can increase risk of exposures to airborne contaminants. In cases of live animal operations, the respiration, bodily functions, and movement of the animals are all considered aerosol-generating activities that increase exposure risks for workers. Because all aerosols will eventually settle, housekeeping and sanitation of work areas where aerosol-generating activities occur is very important for minimization of exposures risks.

Wound exposure is a prominent and common route of entry for infectious microorganisms in lab and research operations. Open wounds should always be covered and protected from exposure to animals or microbiological cultures. Wounds that become red and hot to the touch, that do not heal normally, or that do not show signs of improvement within 7 day time period should be seen by a doctor at earliest sign of concern. All employees who work in agricultural operations, particularly those involving animals, are strongly encouraged to obtain vaccination for tetanus.

Allergens and opportunistic pathogens - Some organisms are not specifically pathogenic, but they may cause dangerous allergic reactions or obstructions in human systems if they gain access to and colonize certain parts of the body. These organisms which may only be hazardous in some people may be referred to as allergens or opportunistic pathogens. Allergic reactions may appear suddenly and severely in the cases of some allergens. Whenever working around flowering plants, live cultures of non-pathogenic microorganisms, invertebrate insects, live animals, or animal wastes employees should take measures to minimize creation of aerosols and avoid breathing dusts and mists of biological materials.

Quarantined and regulated pests - When working with organisms that are not harmful to human health, but pose a threat to the health or plants, animals, or the enforcement, one must consider the route of exposure as well. In these cases, the route of exposure is the route by which the pathogen, pest, or regulated organism, may gain access its desired host or habitat. This route may be via water flow from a research plot, via transfer from the bottom of one's shoe in the greenhouse, via transfer from one's wet truck tire in the field, or via escape of

invertebrate pests on one's clothing. Additionally, one's behavior inside labs and greenhouses also matters. Sloppy work leads to invertebrate infestations of stored materials and contamination of floors and common spaces until eventually the pest is causing trouble with other experiments and in danger of spreading to the local area. In many cases, the same safety measures that are used to protect human health will also assure that plant pests and animal pathogens stay within the confinement of one's research operation. Even when biological materials aren't a threat to human health, the principals and practices of biosafety and containment are important to assure the safety of local agricultural commodities, the trust of industry cooperators, and the continued ability to conduct critical research.

Safety Controls for Biological Materials

Safety controls may be used to protect employees from exposure to biohazards in the course of their work. In cases where the biological materials pose little threat to human health, safety controls may be required to prevent unintentional release of biological materials to the environment where they can make contact with susceptible or receptive hosts. Safety controls are prioritized according to the hierarchy of controls. The most effective control for biohazard risk is to avoid or eliminate the biohazards or regulated materials from the work. If pathogenic or regulated biological materials must be used, or are the subject of the research itself, other controls must then be considered to reduce the risk. Engineering controls are the next line of defense followed by administrative controls. If the exposure or release risk cannot be sufficiently lowered by use of engineering and administrative controls, then use of personal protective equipment may be required.

Elimination, substitution, or biological inactivation as a safety control

The most effective control for biohazards is to not use them in the first place. Examples of this method of risk management may include limiting work to locally endemic pests inside of a single county, using attenuated strains of pathogens which have been modified to not cause disease, collecting non-viable samples for analysis, or using a validated method to biological inactivate the viable biological materials before use or storage.

Whenever non-pathogenic or attenuated microorganisms are substituted for closely related pathogenic strains and all organisms are stored and used in the same lab or project, careful attention must be placed on labeling and identification of cultures in storage and in use. Experiments should include routine measures for confirming the identity of the biological agents to verify that they are non-pathogenic.

Biological inactivation refers to eliminating the ability of the organism to persist in the environment or pass on its genes. Biological inactivation procedures must be established for any hazardous or regulated biological materials used in research in order to safely dispose of material at the conclusion of the project. Whenever viable materials are biologically inactivated, a standard method must be used or the method in use must be tested and validated to inactivate the targeted biological materials. Standard methods of biological inactivation are autoclave treatment, heating to specific temperature for specific amount of time, freezing at -80C, and use of disinfectant chemicals (must use correct concentration and contact time). Disinfectant chemicals or physical methods are most often used to kill microorganisms. Some arthropods may be frozen. Plants and plant parts may be composted or ground up, but seeds and pollen might also require control or higher level of destruction such as autoclave or incineration. Imported or contaminated soils may require biological inactivation via heat to destroy any living organisms or specific experimental organisms before storage or disposal. It is important to consider that all methods do not work on all materials. If published literature verifying the inactivation method

does not exist, the method must be tested and validated by the PI's lab before it can be accepted as effective for biological inactivation of viable materials.

Engineering controls

Engineering controls are the next line of defense if the hazardous or regulated materials cannot be eliminated or substituted. Engineering controls are equipment and physical facility features that ensure control of biological materials and can be externally tested and validated for effectiveness. Engineering controls commonly used to contain or isolate biological materials are often minimal or unnoticeable at lower hazard levels, but can be very complex and expensive to implement for high hazard work. Examples of engineering controls used for biohazard protection include the primary laboratory room with a closed door and inward airflow from areas of least hazard towards areas of highest hazard work, use of HEPA-filtered enclosures such a biosafety cabinets or glove boxes to isolate work that may generate aerosols, safety eyewashes for irrigation of the eye, and use of autoclaves to sterilize materials. Use of secondary leak-proof containers and locked freezers for storage of biological materials may also be considered engineering controls.

Biosafety level (BSL) is a term that refers to the suite of facilities, equipment, and practices that may be applied to control exposure to biological hazards. Biosafety levels have been established to identify laboratory safety controls for protection of human or animal health. However, BSL designations do not always take threats to crop health posed by plant pests into consideration. There are four biosafety levels and these roughly correspond to the risk group classification of organisms. Biosafety level one (BSL1) facilities are appropriate for work with risk group of organisms. Most plants, plant pathogens, and plant-associated invertebrates can be used safely at BSL1, but additional controls may be required to prevent environmental release of pests. Biosafety two level (BSL2) facilities have more equipment and practices in place to protect human health because risk group two agents are in use. UC ANR does not have any facilities that meet biosafety level three (BSL3) or biosafety level four (BSL4) requirements. This level of high hazard work must be conducted on a UC campus in an appropriate facility.

Facility guidelines for applying engineering controls to biosafety or containment needs at ANR facilities are summarized in Appendix 2c.

Administrative controls

Administrative controls are the next line of defense if engineering controls are not feasible or cost effective based upon the level of risk posed by the materials. Administrative controls are practices and procedures that people must perform in order to assure protection or containment of biological materials. For biological research involving low hazard materials (that do not cause human disease), administrative controls are commonly applied and may be quite extensive. Training, creating and using standard operating procedures, medical surveillance programs, signage, regulatory permits, internal and external inspections, handwashing practices, and maintaining accurate inventories of biological materials in storage are all examples of administrative controls. Some forms of administrative controls such as regulatory permits for use of pathogens or GMOs are enforceable as law with fines and imprisonment. Administrative controls also vary widely depending upon the risk posed by the agents.

Laboratory signage

Entry door signage is a valuable and often overlooked administrative control. Each lab and research location controlled See section 1 for information on entry door signage and requirements for door signs. Entry door signage for research areas that contain regulated or hazardous biological materials should communicate requirements for people to safely enter and exit the space without exposing themselves or others to biological hazards; these requirements may include use of lab coats and protective outerwear while in the lab or use of a disinfectant footbath upon exit from an area. Entry signage should also communicate any restrictions or prohibitions on use of personal electronics or storage of personal items such as backpacks and purses in research areas.

Inventory of biological materials

An inventory of cultures retained for long term storage (archived cultures at 4C, -20C or -80C) must be maintained for each lab that handles or stores pathogenic or genetically modified organisms. This inventory should include pathogens of humans, animals, and plants as well as closely related organisms that may be confused with or used in conjunction with pathogens (such as insect vectors). A complete list of genetically-modified organisms used or stored in labs or other research facilities (greenhouses growth rooms, post-harvest storage facilities). In addition to pathogens and GMOs, any biological materials such as plant samples or microbial cultures that may be subject to spoilage or infestation by pests must be labeled to indicate contents and responsible party.

Biological Use Authorizations (BUA), standard operating procedures, and containment plans

This manual is intended to serve as a safety manual for laboratories which do not use any biological materials of concern such as pathogens, GMOs, or quarantined and regulated pests. If hazardous or regulated biological materials are in use, specific SOPs must be developed to describe the safety and containment features that are required to control the hazards posed by the biological materials. When required for the work, a current Biological Use Authorization that has been reviewed and approved by an IBC, fulfills the requirement for a biosafety/containment plan. If a BUA is not required for work with quarantine or regulated biological materials, an SOP or containment plan may still be required under state or federal regulations if those materials pose a threat to living organisms or the environment.

A template for a biosafety and containment plan is provided as Appendix 2a in this section lab safety manual. A biosafety SOP is required for work with animals or animal materials that poses disease hazard to employees (see requirements for work with live vertebrate animals). A containment SOP is required for any USDA plant pest permit application (see Guidelines for Plant Health Protection). Whenever containment of plant pests is required to prevent serious detrimental effects upon susceptible hosts in the local environment, a containment SOP is advised.

Biosafety training resources

General biosafety courses available through UC Davis learning management system (requires UCD log-in ID)

UC Davis has two online biosafety training modules available for BSL1 lab users. The content is tailored to UC Davis campus, but the basic principles and practices of biosafety are described.

Go to: lms.ucdavis.edu and search for:

- Proper Handling of Materials at Biosafety Level 1 (DACS-L-112713-SAFSVC) This course is required for those whose work in research and related projects involve microbiological materials and recombinant or synthetic nucleic acids that can be safely handled at BSL1.
- Biological Safety for Plant Research (DACS-L-PLANTBIO-SAFSVC) This course provide basic background for those who work with plant pathogens and GMOs in BSL1 labs and greenhouses.

Greenhouse sanitation

Purdue University has published useful guidance on greenhouse sanitation which is available free online here:

Greenhouse Sanitation for Disease and Pest Management (Purdue University extension publication): https://www.extension.purdue.edu/extmedia/ho/ho-250-w.pdf

USDA-APHIS permit acquisition for plant pests

USDA-APHIS-Plant Pest Quarantine (PPQ) division has published online learning modules to assist researchers in acquisition of USDA-APHIS-PPQ permits for regulated items such as microbes, insects, soil, and plants:

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/ct_modules

Personal protective equipment

Personal protective equipment is considered after all other levels of controls have been assessed and applied. PPE may be used for human health protection or to prevent cross-contamination or release of biological materials used and stored in labs and research facilities.

University of California policy states that minimum lab attire for anyone entering a lab is: closed toed shoes and full length pants.

Gloves, lab coat, and eye protection for splash hazards are standard protective equipment for use in BSL1 labs. Lab coats may be cotton or cotton-polyester blends. Use of human pathogens or blood may necessitate use of liquid impermeable lab coat. Use of highly flammable chemicals in conjunction with biological materials requires use of flame retardant lab coat. Standard nitrile disposable gloves protect skin from biohazard exposures in labs. In situations where extra protection is desirable thicker gauge gloves can be used or employees can wear a second pair of gloves on top of the other (double-gloving). Eye protection such as splash goggles is required if there is chance of splash to the eyes. Respirators can provide protection from inhalation of airborne biohazards.

Respiratory protection

Any use of respirators for protection from biohazards requires full participation in the respiratory protection program including a medical evaluation for use of respirator and annual fit test and training. Typically, respiratory protection is not needed in a laboratory. Under most circumstances, safe work practices, small scale usage, and engineering controls (fume hoods, biosafety cabinets, and general ventilation) adequately protect laboratory workers from chemical and biological hazards.

Under certain circumstances, however, respiratory protection may be needed. These can include:

- An accidental spill such as:
  - a chemical spill outside the fume hood
  - a spill of bio-hazardous material outside a biosafety cabinet
- Performance of an unusual operation that cannot be conducted under the fume hood or biosafety cabinet.
- When weighing powdered chemicals or microbiological media outside a glove box or other protective enclosure. Disposable filtering face-piece respirators are generally recommended for nuisance dusts. If the chemicals are toxic, contact EH&S for additional evaluation.
- When exposure monitoring indicates that exposures exist that cannot be controlled by engineering or administrative controls.
- As required by a specific laboratory protocol or as defined by applicable regulations.

Because there are numerous types of respirators available, and each has specific limitations and applications, respirator selection and use requires pre-approval by EH&S. Any use of respirators for protection from biohazards requires full participation in the respiratory protection program including a medical evaluation for use of respirator and annual fit test and training. Use of filtering face masks under voluntary use provisions for protection from nuisance dusts and non-hazardous materials should be registered with EH&S.

Because wearing respiratory equipment places a physical burden on the user, laboratory workers must be medically evaluated prior to wearing respiratory equipment. Certain individuals (e.g., persons with severe asthma, heart conditions, or claustrophobia) may not be medically qualified to wear a respirator. Upon enrollment in Respirator Training and Fit Testing, the employee will be sent the appropriate medical questionnaire. The completed medical questionnaire will be evaluated before the employee proceeds with the training. NOTE: This medical questionnaire is confidential. The employee will be provided additional information on who to contact for follow up questions.

After successful completion of the medical evaluation, the employee will be trained and fit tested by EH&S. Training topics include:

- Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;
- What the limitations and capabilities of the respirator are;
- How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;
- How to inspect, put on and remove, use, and check the seals of the respirator;
- What the procedures are for maintenance and storage of the respirator;

- How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and
- The general requirements of the respiratory program.

Finally, a qualitative or quantitative fit test is conducted by EH&S for each respirator user. The fit test ensures a proper face to face piece seal for each individual and his/her mask. Fit testing is done in accordance with Cal/OSHA regulations (8CCR5144) (http://www.dir.ca.gov/title8/5144.html).

An annual refresher is required for the medical evaluation, respirator training, and fit testing. In addition to the annual training refresher, a more frequent re-training, fit testing or medical evaluation must be performed when any of the following occur:

- Changes in the workplace or the type of respirator render previous training obsolete;
- Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill;
- Any other situation arises in which reevaluation appears necessary to ensure safe respirator use;
- Facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight; or
- An employee reports medical signs or symptoms related to their ability to use a respirator.

Storage, maintenance, and cleaning of PPE

Contaminated PPE can pose an exposure hazard to the wearer as well as a risk for release of pests to the environment. Protective equipment used in labs should be kept in the lab space or other research location unless there is a safety need to wear it outside of the lab.

Gloves used in labs should be discarded inside of the lab into the appropriate waste container. If gloves may be contaminated with microbial agents or plant pests, measures must be taken to decontaminate the waste prior to disposal outside the lab.

Safety eyewear and face shields should be periodically cleaned with disinfectant cleaning wipes and maintained in a clean and useable condition. Eyewear and face shields should never be stored with the viewing lens/panel down, as this can cause scratching on the lens surface.

Used lab coats must be stored in labs or research areas and never inside of offices or food storage areas. Lab coats must never be taken home for cleaning. Lab coats must be collected and laundered at the worksite (in a designated washing machine) or picked up for routine laundering by a vendor. Heavily contaminated clothing may need to be disinfected before transfer to dirty laundry. In such cases, lab coats can be pre-treated in 10% bleach, autoclaved, or frozen to eliminate the pests or microbes of concern.

Guidelines for Human and Animal Health Protection

Guidelines for human health protection in laboratory research are published by the U.S. Centers for Disease Control (CDC) in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th Edition, 2009). This publication is available free online (https://www.cdc.gov/biosafety/publications/bmbl5/) and is considered the reference text for biosafety practices.

Section IV of the publication describes the suite of control measures and facilities appropriate for various levels of lab research involving microorganisms, animals, and other potentially biohazardous materials.

Laboratories are classified into 4 "biosafety levels" based on the protective measures applied to the work. Biosafety level one laboratories are designed for use of lowest hazard biological materials, or materials which are not known to cause disease in healthy adults. Microorganisms are also classified in a similar manner into four risk groups according to their relative level of ability to cause disease in humans. Risk group one organisms are those organisms which are not known to cause disease in healthy adults. Some risk group one organisms may cause disease in plants, non-human animals, or in humans with compromised immune systems. Therefore standard precautions are always observed in all work with viable microorganisms in laboratories.

Any significant deviations from standard practices described below, work with pathogens, or work with genetically modified organisms must be described in a biosafety plan/SOP, regulatory permit, or Biological Use Authorization (BUA) that has been reviewed and approved by a UC Campus Institutional Biosafety Committee. This additional project-specific or agent-specific safety information should be included in the lab safety manual and must be available to lab users for review and training purposes.

The following standard practices, safety equipment, and facility requirements apply to biosafety level one labs and research spaces.

Standard Microbiological Practices for Biosafety Level One (BSL-1) Labs (from BMBL 5th ed.)

1. The laboratory supervisor (PI) must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors (PIs) should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
    a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
    c. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
    d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport.
    a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
    b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents (that cause disease in healthy humans) are present. The sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor (PI) or other responsible personnel. Labs working with plant pathogens, GMOs, or other regulated plant materials must post research spaces with signage to indicate restricted access areas that require prior authorization for entry and any special requirements for entry and exit to the work space. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.
11. The laboratory supervisor (PI) must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.

Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

Safety Equipment for BSL – 1 Labs (Primary Barriers and Personal Protective Equipment)

1. Special containment devices or equipment, such as biosafety cabinets (BSCs), are not generally required.*
2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BSL-1 workers should:
   a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
   b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
   c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

Laboratory Facilities (Secondary Barriers for BSL – 1 Labs)

1. Laboratories should have doors for access control.
2. Laboratories must have a sink for hand washing.
3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
   a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
   b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5. Laboratories windows that open to the exterior should be fitted with screens.

Note: Mandatory requirements for special handling/disposal of personal protective equipment, special facilities (secondary barriers), and use of primary barriers such as biosafety cabinets may be set by regulatory agencies (USDA, CDFA) or by UC campus Institutional Biosafety Committees (IBCs) that review work with plant or animal pathogens.

Requirements for work with live vertebrate animals, carcasses and tissues, or untreated waste

Research involving live animals may require additional review by an Institutional Animal Care and Use Committee (IACUC) that examines risk posed to animal health and welfare. Any animal operations that include employee exposure to animals, animal tissues and body fluids, or untreated waste from animal housing operations may also fall under the purview of the CalOSHA aerosol-transmissible disease standard which requires a site-specific safety plan to address the disease hazards.

Institutional review

In keeping with USDA regulations and UC standards for ethical care and use of animals in research, teaching, and demonstration most uses of live vertebrate animals in lab research require review and approval by an Institutional Animal Care and Use Committee (IACUC). Other uses of live animals outside of laboratory research may also require institutional review. If review is required, an Animal Use Protocol (AUP) must be submitted for review and be approved by the IACUC before work with live animals can commence.

Guidelines for animal health and ethical treatment of animals are published by the Federation for Animal Sciences and available free online for most species. Two guides are available: One for agricultural animals and one for lab animals used on research.

Guide for the Care and Use of Laboratory Animals (8th ed., 2011) is available here: https://www.aaalac.org/resources/Guide_2011.pdf

Guide for the Care and Use of Agricultural Animals in Research and Teaching or the "The Ag Guide" (3rd ed. 2010) is available here: https://www.aaalac.org/about/Ag_Guide_3rd_ed.pdf

The local UC ANR Research Advisory Committee (RAC) and UC ANR EH&S must be notified of initial application and kept apprised of the ongoing status of any active IACUC-approved research conducted at UC ANR facilities or through UC Cooperative Extension (UCCE) Offices. Principal investigators who are based at a UC campus and conducting research with live animals at an ANR location (or through UCCE) must request review (or exemption from review) from the IACUC at their home campus. UC ANR researchers who do not have an affiliation or appointment with a UC campus must have their work reviewed by the UC Merced IACUC.

If a principal investigator is unsure whether their work requires IACUC review, they should complete the "Determination of Need for Animal Use Protocol" (Appendix 2b) from the Institutional Animal Care and Use Committee University of California, Merced (UC Merced). For help in preparing an AUP, or for advice about the laws, regulations, and policies that may affect your proposed use of animals, please contact the IACUC office at rci@ucmerced.edu or 209-383-8655. For assistance in planning specific animal care or use procedures (e.g., use of anesthetics or analgesics, surgical procedures, special animal care requirements, transportation, etc.), please contact the UC Merced Attending Veterinarian at 209-228-4040.

Zoonotic disease exposure awareness

In addition to institutional review for the safe and ethical use of animals, the potential for exposure to zoonotic disease agents must be assessed and addressed. Zoonotic diseases are diseases which can be passed from animal species to humans. The infectious animals may or may not have symptoms of illness, with some diseases only causing serious illness in humans. Working with live animals, or handling and storage of animal carcasses, tissues, and bodily fluids may pose risks for exposure to zoonotic disease agents, especially when aerosol-

generating processes are applied to viable biological materials. Storage of animal carcasses can also pose risks for exposure to disease through parasitic vectors such as fleas, mites, and ticks.

When employees are exposed to animal materials that pose zoonotic disease risk, supervisors and employees must follow the requirements of the Aerosol Transmissible Disease Standard (8CCR5199-Laboratory, 8CCR5199.1-Zoonotic). This California regulation sets forth requirements for work in laboratories and as well as work with potentially infectious animal samples outside of lab settings. If research activities fall under the scope of the regulatory standard, a formal written safety plan is required and must be available to employees for reference and training purposes. This safety plan should include a description of the nature of the biological hazards and routes of exposure, the work classifications or employees who may be exposed, safety practices to prevent disease exposures, information on medical services, and medical surveillance requirements. This manual, along with documentation of site-specific hazard assessment, PPE requirements, and SOPs, should fulfill requirements of the aerosol-transmissible disease standard (see page iii - "Required Elements of a laboratory/research biological safety plan (8CCR5199)").

Human health and safety guidelines for use of animals in research are included in the BMBL, see above section regarding protection of human health. In addition to the BMBL, the National Association of State Public Health Veterinarians Veterinary Infection Control Committee has published a compendium of standard precautions for zoonotic disease exposures in 2015. This document may serve well for non-lab settings, animal husbandry, and field work involving wild animals. Relevant portions of this document can be used to inform site-specific work practices and added to this manual as appendices in order to fulfill requirements for zoonotic disease information and training.

Compendium of Veterinary Standard Precautions for Zoonotic Disease Prevention in Veterinary Personnel
http://nasphv.org/Documents/VeterinaryStandardPrecautions.pdf

Laboratory work (involving animals or animal-source materials)

In general laboratory work involving animals at UC ANR is limited to studies of health animal populations. *Intentional culture or manipulation of pathogenic organisms requires specific approval from a UC campus Institutional Biosafety Committee (IBC).* Intentional culture of microorganisms from animal samples may pose zoonotic disease exposure risk and should only be conducted in a Biosafety Level Two (BSL-2) facility. If a BSL-2 facility is not available, a biosafety cabinet may be used along with enhanced biosafety (BSL-2) practices in a controlled access lab facility.

Disposal of animal carcasses and waste products must be conducted in accord with local public health and agricultural codes. Disposal of potentially infectious waste or animal carcass waste requires a specific waste management plan and may require a contract with a waste vendor. Such plans and vendor agreements must be set up by principal investigators prior to commencing work with any animal materials.

Lab safety guidance and precautionary practices for handling of animal samples that may contain pathogens can be found in the two CDC resources linked below:

- *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th Edition, 2009) is available free online here: https://www.cdc.gov/biosafety/publications/bmbl5/)

- *Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories (MMWR Supplements, January 6, 2012 / 61(01);1-101)* is available for download here: https://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm

Handling and storage of environmental samples and plant materials (human health hazards)

The environment is rich in microbial diversity. Soil, water or plant samples may contain microbial species that can affect human health either as opportunistic pathogens or as chronic irritants and allergens. Exposure risk potential is higher when aerosol-generating activities are applied to materials or when microorganisms are cultured from the crude materials. Inhalation of aerosolized plant samples, soils, and water samples should be avoided. Airborne plant materials and soils may contain bacteria and fungi or they may raise the likelihood and risk of allergies in employees. Ventilation and sample handling controls should be used wherever feasible to limit exposure to aerosols. If engineering and administrative controls do not sufficiently reduce exposure hazards, employees may be advised or required to use respiratory protection (N95 filtering facemask). Pure cultures of isolates from plant, soil or other environmental samples should always be handled with caution, until they are verified as non-pathogenic.

Storage of unprocessed samples may also pose human health hazards if fungi or bacteria are allowed to grow in the sample materials. Any stored samples should be labeled with owners contact information and date. Materials must always be stored in sift-proof leak-proof containers.

Guidelines for Plant (Crop) Health Protection

Regulations and enforcement - Plant health protection regulations are established by the California Department of Food and Agriculture and the US Department of Agriculture – Animal Plant Health Inspection Service (USDA – APHIS). USDA APHIS regulates importation, exportation, and interstate movement of plant materials, soils and other items that may pose a threat to plant health. CDFA sets regulations for movement of these materials into the state and between the counties within the state. CDFA regulations are enforced by agricultural commissioners in each county.

Penalties for violation of agricultural regulations can be severe, impacting viability of research operations for decades following an incident. Penalties may include seizure or destruction of research materials, crop destruct orders issued to local farmers, monetary fines, and imprisonment.

The principles of plant pest containment – The goal of plant pest containment is to prevent the plant pest from coming in contact with susceptible hosts. While some airborne fungi and bacteria may pose risks for infection, most plant pests do not pose serious disease risk for humans. The goal of containment is to prevent release of pests from the lab location. Plant pests may be microbial agents such as bacteria fungi and viruses, water-borne invertebrates such as nematodes, or insects that crawl or fly; pests may escape labs on personal items such as back backpacks, on clothes, on the soles of shoes, in one's hair, on one's hands, on plant materials, in soil, in water effluent, or they may walk or fly out open windows and doors. For these reasons, personal items should not be brought into or stored in research areas where quarantined or regulated materials are used. Proper use of personal protective equipment such as lab coats and gloves is essential to avoid accidental release of pests and contamination of materials. Storage of personal food items in the same location as plant samples that are used for research purposes poses a risk for accidental exposures or for pest release.

A Practical Guide for Containment: Plant Biosafety in Research Greenhouses (2008), published by Virginia Tech University, provides guidance appropriate for containment of all level of plant pathogens and GMOs used in plant research. Of particular utility is a summary table of greenhouse containment features that is provided in section VI of the manual linked below.

A Practical Guide for Containment: Plant Biosafety in Research Greenhouses (2008):
https://vtechworks.lib.vt.edu/bitstream/handle/10919/78423/ISBPracticalGuidePlantContain.pdf?sequence=1&isAllowed=y

Plant pest standard operating procedures and containment plans

USDA-APHIS-PPQ has published containment guidelines for various types of plant pests. Whenever containment of plant pests is required to prevent serious detrimental effects upon susceptible hosts in the local environment, a containment SOP is advised. A containment SOP is required for any USDA plant pest permit application. A template for a containment or biosafety plan is provided as an appendix to the lab safety manual. Containment facility SOPs that describe the practice, equipment, and facilities used to control plant pests should be based upon the principles outlined in the following USDA containment manuals:

USDA - APHIS - PPQ Containment Guidelines for Viral Plant Pathogens and their Vectors
https://www.aphis.usda.gov/plant_health/permits/downloads/plant_viral_pathogens_containment_guidelines.pdf

USDA - APHIS - PPQ Containment Guidelines for Plant Pathogenic Bacteria
https://www.aphis.usda.gov/plant_health/permits/downloads/bacteria_containment_guidelines.pdf

USDA - APHIS - PPQ Containment Guidelines for Fungal and Oomycete Plant Pathogens
https://www.aphis.usda.gov/plant_health/permits/downloads/plant_fungal_pathogens_containment_guidelines.pdf

USDA - APHIS - PPQ Containment Guidelines for Plant Pathogenic Nematodes
https://www.aphis.usda.gov/plant_health/permits/downloads/nematodes_containment_guidelines.pdf

USDA - APHIS - PPQ Containment Guidelines for Non-indigenous biocontrol arthropods
https://www.aphis.usda.gov/plant_health/permits/downloads/arthropod_biocontrol_containment_guidelines.pdf

USDA - APHIS - PPQ Containment Guidelines for Noxious weeds and parasitic plants
https://www.aphis.usda.gov/plant_health/permits/downloads/noxiousweeds_containment_guidelines.pdf

Genetically-modified Organisms (GMOs)

Research materials that have been subject to genetic modification through experimental means must be assessed for risk posed to health and the environment. Public institutions such as the University of California must adhere to state and federal regulations and guidelines in production, use, and transfer of GMOs.

Experimental production of genetically-modified organisms (by addition or use of synthetic nucleic acid tools) requires specific review and authorization from UC ANR EH&S. Most work with recombinant or synthetic nucleic acids requires review and approval of a UC Campus IBC. Specific requirements for the work may be set by the

campus committee. Principal investigators are responsible for fulfilling the containment requirements set forth by the IBC and for immediately notifying UC ANR EH&S and the UC Campus IBC if containment requirements cannot be met or there has been an accidental release of regulated research materials.

All genetically-modified organisms must be rendered biologically inactive prior to disposal into the land fill. Edible materials produced by experimental GMOs must be destroyed and prevented from ever entering the food chain. Any accidental release of GMOs or possible contamination of the food chain with experimental materials must be reported immediately to EH&S. Reporting to federal or state agencies may be required as well.

Indoor research (labs, greenhouses, growth rooms, post-harvest facilities, storage, insectaries, etc)

"As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the *NIH Guidelines*."

Laboratory production, use and storage of Genetically Modified Organisms in labs and plant growth areas must be conducted according to guidelines set for the National Institutes of Health Office of Biotechnology Activities (NIH OBA).

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids or "the NIH Guidelines" provide specific guidance for containment and biosafety for **indoor research locations**. This document is available here: https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf

Guidelines for containment of GMOs in research involving whole plants is found in appendix P of the NIH guidelines: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948504

Outdoor research and shipping via commercial carrier

Importation, interstate movement, or Intentional outdoor release of regulated GMOs (GMOs that have not gone through the process to become commercially available products) requires specific approval from the Biotechnology Regulatory Service of USDA-APHIS (USDA-APHIS-BRS). See also: Transportation and shipment of biological materials below.

USDA-APHIS-BRS Guidance for Permit Applications (March 2017) is available here: https://www.aphis.usda.gov/biotechnology/downloads/permit_guidance.pdf

USDA-APHIS-BRS Guidance for Notifications (March 2011) is available here: https://www.aphis.usda.gov/biotechnology/downloads/notification_guidance_0311.pdf

In order to support compliance with federal regulations in the event of an emergency or natural disaster, UC ANR EH&S should be notified of any USDA-permitted outdoor plantings or significant storage of regulated GMOs at ANR facilities.

Standard Procedure for Biological Spill Clean-up

Prior to work with any biological materials, it is essential that employees know how to clean up and report any hazardous spills or accidental release outdoors.

Before you decide to clean up the spill, ask yourself…

- Is the spill indoors and small enough that you can clean it up without assistance?
- Have you checked yourself and others nearby the spill for spatter or shoe contamination?
- Have you alerted the lab personnel and passersby (for spills in corridors)?
- Have you located the spill kit and verified that you have everything you need?
- Are you trained to clean-up the material that has spilled?

If you answered "yes" to the questions above and it is appropriate for you to clean up the spill, you may proceed as outlined below:

1. Wear appropriate PPE to clean spills – gloves, eye protection for splash or spray hazards, and a lab coat are minimum for cleaning up a hazardous spill. Remember that you may need protection from the disinfectants as well as the biological materials.
2. If the spill involved broken glass, pick up the large pieces with the forceps or egg tongs and dispose in a hard-walled sharps container. Handle with care!
3. Distribute paper towels around the periphery of the spill, then towards the center. Use a gloved hand (or the forceps or egg tongs) to push paper towels into recesses where spilled material may have flowed.
4. Apply appropriate liquid disinfectant (10% bleach, greenhouse disinfectant, virkon, etc)
5. When the spill is fully covered with paper towels, spray or very carefully pour 10% bleach or other approved disinfectant on the paper towels.
6. Allow the spill to have the appropriate amount of contact time for disinfectant to inactivate biological agents (30 minutes for 10% bleach).
7. Pick up the paper towels with gloved hands (or large forceps or egg tongs) and put them in the appropriate waste bag. Change gloves and put used gloves in bag as well.
8. Spray or carefully pour 10% bleach or other approved disinfectant on the surface residue.
9. Wipe up the residue with paper towels and place in appropriate bag. Small bits and pieces of broken glass should be entrained in the wet paper towels and discarded into the waste bag. Pieces too large or heavy to entrain must be discarded in a sharps container.
10. Repeat steps 8-9 at least once to assure that residual contamination from the spill is eliminated.
11. Seal and transport the waste collection bag to the appropriate autoclave or waste accumulation site.
12. If broken glass was disposed in a sharps container, seal the container permanently, decontaminate the exterior with the sprayed liquid disinfectant, and transport the sealed container to dumpster or request a sharps waste pickup from hazardous waste vendor (e.g., Stericycle).
13. Clean and disinfect the forceps or egg tongs and any other non-disposable items before returning them to the spill kit. If possible, autoclave the forceps or egg tongs before returning them to the kit.
14. Report the spill to your supervisor and location safety coordinator. Some biological materials such as GMOs or infectious agents, if spilled outdoors, may require notification of UC campus IBC or local agricultural authorities.

Transportation and Shipment of Biological Materials

Movement within the state of California

Transportation and shipment of human or animal pathogens requires specific training and is regulated under federal transportation regulations. Contact EH&S if shipment or transportation of known or suspected animal or human pathogens is necessary.

GMO's that are produced within the state of California may be transported within the state of California following standard precautions to prevent release or establishment in the outdoor environment (see 7CFR340 package requirements below).

Interstate movement and international importation

Importation or movement of GMOs and USDA-regulated plant pests across state lines requires authorization from USDA-APHIS.

Shipment of potentially hazardous plant materials or regulated GMOs must follow requirements set forth in 7CFR 340.7 and 7CFR 340.8 below.

Marking and identity (7 CFR § 340.7)

(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the organism;

(4) Name, address, and telephone number of consignee;

(5) Identifying shipper's mark and number; and

(6) Number of written permit authorizing the importation.

(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to APHIS through any USDA plant inspection station listed in § 319.37-14 of this chapter and shall be accompanied by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cured;

(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and

(4) Number of permit authorizing the importation;

(c) Any regulated article imported into the United States by mail or otherwise shall, at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment.

Container requirements for the movement of regulated articles (7 CFR § 340.8)

(a) General requirements. A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section.

The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 CFR or any other agency of the Federal government.

(b) Container requirements -

(1) Plants and plant parts. All plants or plant parts, except seeds, cells, and subcellular elements, shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrogated cardboard, wood, or other material of equivalent strength.

(2) Seeds. All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) Live microorganisms and/or etiologic agents, cells, or subcellular elements. All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) Volume not exceeding 50 ml. Regulated articles not exceeding 50 ml shall be placed in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) Volume greater than 50 ml. Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may be placed in a single, secondary container. The maximum amount

of micro-organisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) Dry ice. If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) Insects, mites, and related organisms. Insects, mites, and other small arthropods shall be packed for shipment as specified in this paragraph or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) Other macroscopic organisms. Other macroscopic organisms not covered in paragraphs (b) (1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraph (b)(3) or (b)(4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape of organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

(c) Request for a variance from container requirements. A responsible person who believes the container requirements normally applicable to the movement of the person's regulated article(s) are inappropriate due to unique circumstances (such as the nature, volume, or life stage of the regulated article) may submit in an application for a permit, a request for a variance from the container requirements. The request for a variance under this section shall consist of a short statement describing why the normally applicable container requirements are inappropriate for the regulated article which the person proposes to move and what container requirements the person would use in lieu of the normally prescribed container requirements. USDA shall advise the responsible person in writing at the time a permit is granted on the person's request for a variance.

Safe Use and Disposal of Sharps (needles, scalpels, glass pipettes, disposable blades)

Sharps may include needles, scalpels and other sharp pointed objects used in research that may readily puncture the skin. Use of sharps in research requires specific hands-on training and knowledge of disposal practices. Needles should never be re-capped. Needles and disposal blades must be thrown into the waste container once they are no longer of use. Needles and razor blades should never be left stored in common areas where others may accidentally come in contact with them.

Sharps must be collected in a hard-walled spill-proof container that prevents easy access and removal of waste once it is deposited within – whether or not they are contaminated with human blood or human pathogens. Needles, blades, scalpels, and glass pipettes used in non-hazardous lab operations and research cannot be thrown in the regular trash because they pose a puncture risk for others who may handle the trash during or after it is removed from the lab. Needles and similar devices used to puncture skin are also banned from many municipal landfill disposal sites and must be disposed as "home generated sharps waste" through the local sanitation agency or landfill. Sharps used for human blood or contaminated with human pathogens is considered Regulated Medical Waste. Sharps with regulated plant pests, animal pathogens, or sharps resulting from animal care (veterinary) activities may require special treatment such as autoclave sterilization or disposal through a waste vendor.

Biological Waste Handling and Treatment

Biological waste includes any material that once contained or now contains living organisms, or that is a product, portion, or waste of a living or once-living organism. Examples of biological waste may include, but is not limited to: untreated animal carcasses, soiled bedding from animal housing or husbandry operations, untreated animal tissues or body fluids, discarded cultures from labs, dead insects, discarded plant material, or soil. Biological waste may or may not be inherently hazardous. Even non-hazardous biological waste from experiments can become a sanitation concern or can provide a reservoir for establishment of hazardous pathogens or pests if it is not collected and disposed properly.

Regulated biological waste

Disposal of biological wastes that pose a threat to local human health, animal health, plant health, or ecology may be regulated by state and federal agencies. Strict regulations govern handling and treatment of waste that may contain human pathogens or USDA-regulated plant pests. Those wastes are managed under permits issued by the local department of public health (human pathogens) or USDA (animal and plant pathogens). Biological waste that contains GMOs or quarantined and regulated pests (QARP) should never be released to the environment without treatment (or specific authorization for release). This waste must be managed and disposed of as specified by USDA, CDFA, and local agricultural authority.

Regulated Medical Waste and carcass waste

Biological waste that is infectious to humans must be managed and disposed of as medical waste. Regulated Medical Waste is waste which contains human pathogens, human blood or OPIM. This type of biological waste is required to have the biohazard symbol on it and must be handled according to US Department of Transportation (US DOT) Guidelines and the California Medical Waste Management Act. If medical waste is generated as part of the research project, a medical waste management plan is required and all infectious waste must be sealed in bags and transferred to the waste vendor on a weekly basis. Service agreements and contracts must be

established with a medical waste vendor prior to commencing any research that may require or result in generation of medical waste. **The biohazard symbol, the word biohazard, and red waste bags MUST be reserved ONLY FOR MEDICAL WASTE.**

Animal carcasses, tissues, and bodily fluids from animals not known or suspected to harbor diseases must be handled and disposed as carcass waste through an authorized waste vendor. Samples or large volumes of carcass waste that have resulted from a significant animal disease event must be handled as infectious. In cases of animal disease outbreak response, local authorities may enact specific requirements for disposal of animal waste. Service agreements and contracts should be established with waste vendors prior to commencing any research that may require or result in storage of animal carcasses.

Mixed wastes

Mixed wastes are wastes that have radioactive or chemical hazard in addition to biological hazard. Whenever possible, it is best to anticipate and avoid generating mixed wastes. Unless human pathogens, biological waste containing hazardous chemicals or radioactive materials is classified as and considered to be chemical or radioactive waste respectively. Autoclaving or adding bleach to biological waste that also has other hazardous chemicals or radiation present may increase the overall hazard of the waste greatly. Deliberate culture or use of human pathogens is prohibited at UC ANR without specific authorization, thus most uses of radiation or hazardous chemicals in conjunction with human biohazards are also similarly prohibited.

Sharps waste

Sharps waste is managed according to what type of materials may be on the sharps that are discarded. Sharps waste that is generated in research involving human pathogens or human blood and tissue must be managed and disposed of as medical waste sharps. This waste is collected in a sharps container with a biohazard symbol.

Sharps waste that does not contain any human pathogens or body fluids, should be collected in a puncture proof container that prevents access and spillage of waste that is deposited within. A traditional sharps container can be used for collection of non-medical waste sharps, but the container must NOT have a biohazard symbol or the biohazard symbol and word “Biohazard” must be defaced and rendered illegible. Sharps waste containers must be disposed through a licensed waste vendor or through local waste authority that accepts sharps waste.

Unregulated biological waste

Other biological wastes such as daily lab trash containing spent media, plants, and relatively low hazard organisms should be evaluated and treated according to the level of risk posed by the waste. Any type of biological waste may still pose local contamination, disease, or sanitation concerns if not contained and managed properly. Biological waste that does not contain known human pathogens may be treated onsite to biologically inactivate resident microorganisms. Large volumes of pure cultures of locally endemic microbial agents that do not pose a serious detrimental impact to local ecology or agriculture should also be biologically inactivated prior to disposal to the land fill to avoid creating or worsening any local reservoirs of plant pests.

Waste treatment and disposal methods

Any waste treatment methods or procedures in use must be based on established practices or previously published references, and should provide for an objective means to verify efficacy of the treatment.

Sterilization refers to the complete elimination or destruction of all forms of life by a chemical or physical means. This is an absolute, not a relative term. Disinfection or decontamination refers to reduction in the number of target microorganisms, usually by at least a factor of 10^6. Disinfection is expected to eliminate almost all disease causing microorganisms, but might not eliminate all living organisms. Some disinfectants are not effective against bacterial spores and certain types of viruses.

Physical waste treatment

Autoclave treatment (121C 15 psi for minimum 30 minutes) is the preferred method for sterilizing biological waste that is not infectious to humans. Some plant pests and pathogens may be inactivated by dry heat of ovens, by freezing or by passive desiccation.

Whenever autoclaves are relied upon to inactivate plant pests and treat waste, the function of the autoclaves should be verified twice annually by use of biological indicator tests (*Geobacillus sterothermophilus*). This is a requirement for waste that is regulated under USDA permits. Tests must be conducted as specified by manufacturer, with documentation of results and any associated repairs or maintenance on the autoclave preserved as record of compliance.

Biological waste that does not contain human pathogens or body fluids must be autoclaved in autoclave bags that DO NOT have any biohazard symbols or the word Biohazard on them. The biohazard symbol, the word biohazard, and red waste bags MUST be reserved ONLY FOR REGULATED MEDICAL WASTE that poses a threat to human health.

Chemical treatment

Chemical disinfectants commonly used in biological lab facilities include aldehydes, halogen-based disinfectants, quaternary ammonium, phenolic compounds, and alcohols.

Whenever a chemical disinfectant is used, it is critical to mix the solution gently but thoroughly (avoiding splash and pressure build up), and follow the manufacturers instruction for contact time and concentration of disinfectant needed to provide at least a 6-log reduction in viable microorganisms. Use of any chemical disinfectants must include full consideration and assessment for chemical incompatibilities in the waste, as well as disposal or liquid effluent outflow of the used disinfectant mixture to the environment. Many disinfectants listed for horticultural use cannot be released to the environment because they will cause damage to aquatic and amphibious animals. Large volume or highly concentrated bleach solutions may impact local septic or water treatment operations.

Aldehydes (formaldehyde, formalin solution, glutaraldehyde) – Aldehyde chemicals are used to disinfect surfaces and equipment. However, these chemicals are also hazardous to human health. Formaldehyde and formaldehyde solutions (such as formalin) are carcinogens that are hazardous by inhalation. Use of formaldehyde in research requires a written SOP describing the hazards of the chemical, the uses of the chemical, and steps to take to protect one's health from exposures to formaldehyde. Use of a properly functioning and annually certified fume hood is required for use formaldehyde and formalin. Formaldehyde

solutions are sometimes used for long term storage of biological specimens due to the excellent bacteriostatic properties of the chemical. Storage of plant specimens and arthropods in formaldehyde solutions should be avoided unless no other options exist. Alcohol or other less toxic chemicals should be used for archival storage of specimens

Bleach - Household bleach may be used to inactivate small to moderate volumes (1L or less) of liquid culture and suspensions of microorganisms. In general, adding bleach to achieve a 10% final concentration, mixing well and allowing to sit for 30 minutes will inactivate most microorganisms. Local ventilation (a fume hood) may be needed to remove irritant and foul odors during the contact time isolation period. Presence of organic materials, such as soil or bodily fluid, may reduce the efficacy of some chemical disinfectants such a bleach. In such instances, longer contact time or higher concentration may be required for effective disinfection.

Diluted bleach solutions should always be made up fresh. Diluted bleach solutions will lose their disinfectant activity after approximately one week of storage. Chemical test strips can be used to assess the free chlorine left in bleach solutions over time. Bleach can have hazardous chemical reactions if mixed with formaldehyde or with acids or ammonia-based chemicals. Bleach solutions should not be autoclaved.

Iodophors – Iodophor disinfectants include chemicals sold under the names Westodyne, Betadyne, and Povodine-iodine. Iodophors consist of iodine and a solubilizing agent. Iodophor antiseptics are widely used for treatment of wounds. Iodophors provide more sustained release disinfectant power than bleach solutions and are popular in animal husbandry applications. Iodophors can be used in water supplies and foot baths. Iodophor solutions may stain porous plastics.

Quaternary ammonium compounds (Simple Green, Physan 20, Green-Shield) - Quaternary ammonium disinfectants or “quats” include popular greenhouse disinfectants like physan and greenshield. These chemicals are more stable and effective than bleach in the presence of organic material such as soil and plant debris. Quats may leave residue that requires rinsing. If Quats are applied via spray in area of inadequate ventilation, respiratory protection may be required to avoid irritation. Written SOPs should be prepared for any large scale uses of quaternary ammonium products for disinfection.

Phenolics (Lysol, Pine-sol) – These disinfectant chemicals retain high activity in presence of organic materials. They are often used for routine cleaning in areas where virus elimination is important (bathroom, kitchen).

Alcohols (70% ethanol, 70% ispropanol) – Alcohols have been shown to be effective against a wide variety of microorganisms. However. Alcohol solutions are not registered with EPA as disinfectants. Alcohol sprays and wipes can be used for quick surface disinfection. The main drawbacks of alcohol are that it is flammable and it evaporates too fast to provide disinfectant action against many microorganisms. A 70% solution in water is most effective for elimination of bacteria, fungi, and viruses.

In some cases 95%, ethanol is used to facilitate flame sterilization of instruments used in aseptic tissue culture or microbiology work. In this case, heat is the primary sterilization technique and alcohol is a secondary feature. Extreme caution must be employed whenever high concentration alcohol solutions are used in conjunction with open flame. The container of 95% alcohol used as part of flame sterilization must be the smallest volume needed, have a lid that can be quickly placed atop the container (to extinguish any accidental fire and prevent

evaporation/spill hazard when not in use), and the container must be stable enough to avoid easily tipping over in use. Note: A fire retardant (FR) lab coat should be worn if there is danger of igniting one's clothes when using alcohol for flame sterilization of materials.

Destructive processing or analysis methods

Chemicals and extreme temperatures used in processing of samples may also result in biological inactivation of microorganisms such as when plant materials are ground in chemical solvents, frozen in liquid nitrogen, stored frozen at -80C, subjected to boiling temperatures (100C), or subjected to bulk nucleic acid extraction methods.

Disposal through certified hazardous waste vendor

The majority of solid Regulated Medical Waste (human infectious waste), unknown potentially infectious waste, waste containing hazardous pesticides, and sharps waste must be disposed through authorized hazardous waste vendors. Contracts with vendors must be established and implemented prior to generation of any waste that requires disposal through commercial vendors.

Biosafety Definitions (8CCR5199, 8CCR 5199.1, 7CFR340)

AEROSOL. A suspension of liquid or solid particles in the air, including droplets, droplet nuclei, fomites, and dusts.

AEROSOL TRANSMISSIBLE PATHOGEN (ATP). A pathogen that is transmitted by liquid or solid particles in the air, including droplets, droplet nuclei, fomites and dusts.

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

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

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.

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 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 requirements for risk assessments and control measures in vertebrate animal research facilities.

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.

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.

CDC. United States Centers for Disease Control and Prevention.

CONTAINMENT. Enclosure of viable materials within containers or buildings such as bug dorms, greenhouses, or growth chambers.

CONFINEMENT. Control of viable materials within a designated area such as a greenhouse bench or an outdoor field plot.

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

DISIFNECTANT. A chemical or physical agent that is applied to inanimate objects to kill microorganisms. Disinfectants may vary in their ability to kill various types of microorganisms or be ineffective against some type of spore-forming microorganisms.

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 m m in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism.

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.

GENETICALLY MODIFIED ORGANISM (GMO). A organism which has been artificially (experimentally) altered via use of synthetic or recombinant nucleic acid molecules so as to produce a desired characteristic.

HIGH HAZARD PROCEDURES. Procedures performed on a patient that 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. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens.

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.

INTERSTATE. From any State into or through any other State.

INTRODUCE OR INTRODUCTION (USDA-APHIS). To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

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.

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.

MOVE (MOVING, MOVEMENT). To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

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.

OCCUPATIONAL EXPOSURE (ATP-L). 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.

OCCUPATIONAL EXPOSURE (ZOONOTIC). 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.

ORGANISM. Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

OXYGEN DEFICIENT ATMOSPHERE. An atmosphere with an oxygen content below 19.5% by volume.

PERMIT. A written permit issued by a regulatory agency such as USDA APHIS or CDFA. The permit serves as an enforceable contract between responsible party and government agency. Under the authority of the Plant Protection Act of 2000, USDA standard permit conditions apply to all work with suspected plant pests.

PLANT. Any living stage or form of any member of the plant kingdom including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any

parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof.

PLANT PEST. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL (PLHCP). An individual whose legally permitted scope of practice in California allows him or her to provide independently or be delegated the responsibility to provide some or all of the health care services required by regulation.

UNTREATED ANIMAL PRODUCTS, BYPRODUCTS, OR WASTES. Materials derived from animals that have not been processed in a manner that will deactivate zoonotic ATPs the materials may contain. "Untreated animal products, byproducts, or wastes" do not include animal carcasses or portions thereof that have passed an inspection in accordance with the standards of the USDA or CDFA and have been determined to be fit for human consumption.

VECTOR OR VECTOR AGENT.

Molecular biology/biotechnology - Organisms or objects such as DNA/RNA used to transfer genetic material from the donor organism to the recipient organism.

Infectious disease – An organism which transmits disease to other organisms.

REGULATED ARTICLE (USDA APHIS). Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7CFR §340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

RELEASE INTO THE ENVIRONMENT. The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

RESPONSIBLE PERSON (USDA APHIS PERMIT). The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

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.

RESPIRATOR USER. An employee who in the scope of their current job may be assigned to tasks which may require the use of a respirator, in accordance with subsection (g).

STERLIZATION. Complete elimination or destruction of all forms of life by a chemical or physical means.

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.

USDA. United States Department of Agriculture.

USDOI. United States Department of the Interior, or any of its agencies, including the United States Fish and Wildlife Service and the United States Geological Survey.

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.

ZOONOTIC ATP INCIDENT RESPONSE. Operations conducted to control an outbreak of an animal disease involving the destruction and/or disposal of animals infected with zoonotic ATPs and the clean up, decontamination and disinfection of areas and equipment associated with the infected animals or their remains

Appendices and SOPs

Appendices

Appendix 2a – Biosafety Plan / Containment SOP template

Appendix 2b – Determination of Need for Institutional Animal Care and Use Committee

Appendix 2c – Biosafety lab facility design matrix (engineering controls)

Appendix 2d – List of Select Agents and Toxins

Appendix 2e – List Aerosol-Transmissible Disease Agents