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# Laboratory Facilities and Safety Manual Overview:

The GENETWORx Safety Manual is designed to provide users with general health and safety information. Following the guidance outlined in this manual will help prevent illness and injury while protecting the environment. The Laboratory Safety Manual meets Occupational Safety and Health Administration (OSHA) requirements for a Chemical Hygiene Plan as specified in 29 CFR 1910.1450, as well as CAP Requirements for Facilities and outlines appropriate practices, university policies, and other regulations that must be followed in laboratories. The Laboratory Safety Manual is not intended to be comprehensive but should supplement specific procedures developed by the person(s) responsible for unique laboratory hazards.

# Laboratory Safety Committee

## Policy:

It is the policy of GENETWORx that a Safety Committee will be appointed by the Laboratory Director.

## Purpose:

### The purpose of the safety committee is to consistently analyze and improve current safety practices in the Lab. The committee strives to meet its goals through education. Current policies are monitored through weekly meetings of the Laboratory Leadership and monthly meetings of the Safety Committee. The Laboratory safety committee is comprised of each supervisor in each laboratory department. One member of the Laboratory Leadership team will be appointed as the Laboratory Safety Officer. A supervisor may appoint a member of his/her department to represent that department in his or her absence

### The safety committee monitors Laboratory safety conditions and reports these results at each Laboratory Leadership meeting. Safety members also participate in annual lab safety training. All employees including non-members are welcome to participate in the safety portion of the Laboratory Leadership and Safety Committee meetings. The Safety officer will also prepare a safety report for the quarterly QA meeting.

## Objectives:

The major objectives of the Safety Committee are:

### 100 % staff participation in Safety Training on a yearly basis.

### Reduction of blood borne exposures to zero.

### Reduction in accident/injury occurrences to zero

### Reduction of safety compensation cost to zero

Each of these objectives will be measured. Incidents will be reported as they occur at the earliest meeting of the Laboratory Leadership.

## Safety Reports - (Prepared and distributed monthly as applicable)

### Laboratory - Number of Reported Sharps Exposures

### Laboratory - Number of Reported Body Exposures to chemical or infectious agents.

## Quarterly Safety Meeting

### **A review of Safety reports will be performed quarterly**

### **Agenda:** The agenda for the safety meeting is informal but should include the following:

#### Review of Safety Reports:

##### Number of Reported Sharps Exposures

##### Number of Reported Body Exposures

#### Recommendations for improvements submitted to the Laboratory Leadership Team

#### Notice of upcoming inspections as required.

### The responsibility for the safety program rests with the Laboratory Leadership Team which receives backing from the Laboratory Manager, Laboratory Director and CEO

### Responsibilities: The Laboratory Safety Officer and Committee must

#### Develop and implement appropriate procedures, policies, and practices.

#### Ensure that 100% of the employees in their respective departments have been trained in the following:

##### SDS

##### Right-to-Know Laws

##### Universal Precautions

#####  Specimen handling, Glove and Protective Clothing Use

##### Sharps Handling

##### Fire Safety

##### Electrical Safety

#### Ensure that 100% of the employees in the department that they represent have scored an 80% or greater on the Safety Quiz. (Failure to score at least an 80% on the Safety Quiz will require that the employee be retrained.)

#### Monitor procurement, use, and disposal of waste generated by the laboratory.

#### See that appropriate audits are maintained

#### Assist in developing and maintaining adequate facilities, policies and procedures.

#### Know the current legal requirements concerning regulated waste.

#### Seek ways to improve the safety program

#### Ensure completion of Hazard Surveillance Rounds.

#### Perform Biohazard Risk Assessment for all specimens tested at GENETWORx (See Quality Manual Attachment 12.

### The Supervisor has overall responsibility to:

#### Ensure that a departmental representative is in attendance and is a participatory member the Laboratory Safety Committee if the department supervisor is not present.

#### Ensure that workers know and follow safety procedures that protective equipment is available and in working order.

#### Know the current legal requirements concerning regulated waste.

#### Determine the required levels of protective apparel and equipment

#### Ensure that facilities and training exist to prevent possible exposure.

#### Ensure 100% compliance in annual mandatory safety training.

### The Laboratory Employee is responsible for:

#### Planning and conducting each operation in accordance with the institutional procedures

#### Developing good safety habits

#### Completing mandatory safety training and scoring at least an 80 % on each Safety Quiz.

### The Safety Committee will consist of the following positions and/or representatives from the identified departments:

#### Laboratory Manager (serves as Laboratory Safety Officer)

#### Laboratory Supervisors (Laboratory Leadership Team)

#### Legal

#### Clinical Trials

#### Operations

#### HR Director

#### ADI

#### Customer Service

#### Ad hoc members as appointed by the Laboratory Safety Office

## Safety Inspections

Safety Inspections will be conducted monthly by representatives of the Safety Committee, or designees, using the attached Safety Committee Facility Checklist (Quality Manual Attachment 14).

### PRINCIPLE

Laboratory hazards are as varied as the subjects of study in laboratories, and might include poisons; infectious agents; flammable, explosive, or radioactive materials; moving machinery; extreme temperatures; or high voltage. In laboratories where dangerous conditions might exist, safety precautions are important. Rules exist to minimize the individual's risk, and safety equipment is used to protect the lab user from injury or to assist in responding to an emergency.

### PROCEDURE

#### Monthly the safety officer or designee will go over Monthly Safety Check list.

#### Safety officers will physically check each item listed on Checklist (Quality Manual Attachment 14) and sign-off if everything is ok and note any deficiencies.

#### Upon completion of Checklist, Safety officer will initial and sign Check list and turn into the Supervisor.

#### All deficiencies will be documented and fixed immediately.

# Laboratory Access Policy

## Policy

### It is the policy of GENETWORx that the building is locked 24 hours a day.

### Only current active employees of GENETWORx are allowed routine access to the building.

## Employee Access

### Access to be building is restricted to active GENETWORx employees in possession of a swipe entry card or by invitation of employees within the building at the time of the visit.

### After business hours the use of a swipe care for entry must be accompanied by an access code.

### Access Codes and cards are controlled by the Operations Manager. Codes and cards are distributed upon employee hiring as part of the Lab Orientation.

### Upon employee termination all access codes and cards are inactivated per the IT procedure 700.015 Account Creation and Deletion Policy

## Visitor Access

### Visitor may access the building by ringing the doorbell and allowed into the building by an employee.

### All visitors are required to sign in to the visitor log and list their name and the name of the person they are visiting.

### No visitors may be unaccompanied within the lab and shall have no access to personal health information without execution of a business associate agreement (BAA).

# Chemical Hygiene Plan: Hoods

## Hoods

### It is the policy of GENETWORx that chemical and biological hoods must be inspected at least annually. Hoods may need to be inspected more frequently as noted in each specific area of the lab.

### Hoods are provided for employee use with specific chemicals and for bio-hazard protection. Each hood is maintained thru the preventative maintenance program to verify integrity of the system.

### Chemical hood records are posted on each hood and maintained in the laboratory once complete. All records are maintained by GENETWORx and available on request. Hoods not passing inspection will be taken out of service immediately and not used until the hood has passed inspection. It is the responsibility of the employer to repair or replace the unit in a timely fashion so as not to endanger the health and well-being of employees. Good practice uses the following techniques:

#### When concerned about or confirmed malfunction of a hood, discontinue the procedure and use of the hood to avoid inadvertent exposure until corrected by Clinical Engineering.

#### Use a hood for operation that might result in release of toxic chemical vapors or dust.

#### Confirm adequate hood performance before use.

#### Keep the hood closed to the appropriate level to ensure the hood has sufficient air-flow.

#### Avoid storing materials in hoods. Do not allow materials to block vents or airflow.

#### Leave the hood “on” when it is in active use.

### Routine Maintenance:

#### Hood decontamination will be performed each day the hood is in use and it will be documented.

#### Annual or bi-annual hood operation of air flow will be performed.

# Chemical Hygiene Plan: Cleaning up Spills

## Purpose: To provide procedure for properly cleaning chemical spills.

## Procedure

### Spill response kits are located in the Post-PCR Lab. All personnel assigned to these departments should familiarize themselves with the location of the spill kits. They are to be used only in the event of a chemical spill. There are also kits that are specific to certain types of chemicals as well as extra Vermiculite in the Laboratory storage area in the Chemistry Lab. Please do not forget to fill out a spill report form that is Attachment 10 of this procedure.

### Use chemical spill scoop in kit to put chemical waste into Yellow spill kit bucket.

### Access spill kit from closet location to the spill.

### Check S.D.S sheet for the chemical spilled and Quality Manual Attachment 11 (Classification of Spill). If applicable continue. If not applicable or you feel uncomfortable with Clean-up Procedure, contact your supervisor and/or Laboratory Safety Officer. See Note 1 below:

### Ensure that appropriate and adequate safety equipment is worn.

### Sprinkle appropriate chemical or absorbent on spill per instructions located in the Spill Kit.

### Rinse the contaminated area with water (if not reactive per S.D.S. sheet) and put into yellow spill kit bucket.

### Place all used spill equipment into yellow spill kit bucket and seal.

### Label yellow spill kit bucket as used.

### Attach a copy of the SDS to the Spill Kit bucket and notify the Laboratory Safety Officer.

### Fill out spill report form. (Quality Manual Attachment 10) to this procedure.

### **Note 1:** Quality Manual Attachment 11 to determine the category of the spill. The following is mandatory for chemicals in Category A over 1 liter:

#### Call the Fire Dept.

#### Contact Environmental Company:

#### Contact the Director of Operations to evacuate the building if necessary.

# Chemical Hygiene Plan: Eyewash Station and Fire Extinguishers

## Policy:

It is the policy of GENETWORx to provide a safe working environment for Laboratory and hospital employees as well as visitors. Eyewash stations, safety showers and fire extinguishers must meet all Federal, State or local codes.

## Purpose:

To provide policy on the inspections and maintenance of eyewash stations, safety showers and fire extinguishers.

## Procedure

### Eyewash fountains are inspected weekly and records maintained within the laboratory.

### Safety Showers:

#### Safety showers are tested monthly and records maintained by the Safety Committee.

### Fire Extinguishers:

#### Fire extinguishers are inspected monthly in accordance with local fire codes. Inspection records are kept by the Laboratory.

# Chemical Hygiene Plan: Glove Use Policy

## Purpose:

To provide the proper procedure for wearing and removing glovesand prevention of latex allergies.

## Recommendations for Prevention of Latex Allergy

### Latex allergy has increased in the last 10 years, and occurs with relatively high frequency in certain at risk populations, especially health care workers, certain patients, and workers who may be required to use latex products in their day-to-day work environment. Reducing latex exposure to the maximum extent possible minimizes sensitization and development of new latex allergy cases.

### There are three types of reactions that can occur in persons using latex. The most common reaction to latex products is *irritant contact dermatitis.* Irritant contact dermatitis is the development of dry, itchy, irritated areas on the skin, usually the hands. This reaction is caused by irritation from wearing gloves and by exposure to the powders added to them. This reaction is caused by skin irritation from using gloves and possibly by exposure to other workplace products or chemicals. Irritant contact dermatitis is not a true allergy. *Allergic contact dermatitis* also called *chemical sensitivity dermatitis,* results from exposure to chemicals added to latex during harvesting, processing or manufacturing. These chemicals cause skin reactions similar to those caused by poison ivy. The rash usually begins within 24 to 48 hours after contact and may progress to oozing skin blisters or spread away from the area of skin touched by the latex. *Latex allergy* also known as *immediate hypersensitivity,* can be a more serious reaction to latex than the other forms mentioned above. Certain proteins in latex may cause sensitization. Although the amount of exposure needed to cause sensitization or symptoms is not known, exposures at even very low levels can trigger allergic reactions in some sensitized individual.

### Reactions usually begin within minutes of exposure to latex, but they can occur hours later and can produce various symptoms. Mild reactions to latex involve skin redness, hives or itching. More serious reactions may involve respiratory symptoms such as runny nose, sneezing, itchy eyes, scratchy throat and asthma (difficulty breathing, coughing spells and wheezing). Rarely, shock may occur; but a life threatening reaction is seldom the first sign of latex allergy. Such reactions are similar to those seen in some allergic person after a bee sting.

### GENETWORx glove recommendation:

#### Use of ***nitrile*** gloves for general laboratory use. If you are uncertain whether or not ***nitrile*** gloves are compatible for the chemicals you use in your laboratory, contact the Safety Officer for help in selecting the appropriate glove.

#### Use of latex-free products whenever they are available (ie.: tourniquets, oral and nasal airways, intravenous tubing, goggles, surgical masks, rubber aprons, etc.).

#### Implementing the following NIOSH recommendations for preventing latex allergy in the workplace. These recommendations are based on current knowledge and a common-sense approach to minimizing latex related health problems. Adoption of the recommendations, wherever feasible, will contribute to the reduction of exposure and risk for the development of latex allergy:

#### The routine use of latex gloves by registration, accessioning, and medical personnel in low risk situations (e.g. food handling) is strongly discouraged. If you must use latex gloves, choose ***powder free*** gloves with reduced protein content. Only low-antigen latex gloves should be purchased and used. This may reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization.

#### Use appropriate work practices to reduce the chance of reactions to latex.

#### When wearing latex gloves, do not use oil-based hand creams or lotions, which can cause glove deterioration, unless they have been shown to reduce latex related problems and maintain glove barrier protection.

#### After removing latex gloves, wash hands with mild soap and dry thoroughly.

#### Use good housekeeping practices to remove latex-containing dust from the workplace.

#### Take advantage of all latex allergy education and training provided.

#### If you develop symptoms of latex allergy, avoid direct contact with latex gloves *and* other latex-containing products.

**References**

[*NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace*](http://www.cdc.gov/niosh/latexalt.html)*,* National Institute of Occupational Health and Safety [NIOSH].

[*NIOSH: Occupational latex Allergies*](http://www.cdc.gov/niosh/topics/latex/)*,* National Institute of Occupational Health and Safety [NIOSH].

## Gloves Use:

### Must be worn when handling primary specimens.

### Must be worn when handling any items for which there is a likelihood that such handling may result in direct contact with infectious or potentially infectious material;

### Must be worn when the employee has cuts, scratches, or other breaks in the skin and is handling infectious or potentially infectious material, regardless of likeliness of exposure.;

### Must be removed and discarded immediately upon contamination

### Must be removed and discarded immediately upon task completion at each work station (ie BSC, bench space) followed by hand washing with an effective anti-microbial method.

### Must not be reused.

## Perform this procedure for gloving according to the following steps:

### Glove Preparation

|  |  |
| --- | --- |
| **Step** | **Action** |
| **1** | Ensure that hands are clean and dry before they are gloved |
| **2** | Remove any sharp objects such as jewelry from fingers and wrists. |
| **3** | Carefully put on gloves taking care not to tear them. |

### Gloving

|  |  |
| --- | --- |
| Number | Notes |
| **1** | Gloves must be worn under the cuff of the lab coat. |

### Degloving:

|  |  |
| --- | --- |
| **Step** | **Action** |
| **1** | Gloves should be removed upon leaving contaminated work area or when soiled, by turning them inside out as they are removed. |
| **2** | Take care not to touch any contaminated portion of the gloves. |
| **3** | Discard gloves immediately after removal in a contaminated waste container. |

# Blood Borne Pathogens

## Policy:

### It is the policy of GENETWORx that Universal Precautions, as outlined below for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings will be observed at all times.

### GENETWORx is committed to providing a safe working environment for its staff. This Exposure Control Plan (ECP) for Bloodborne Pathogens is provided to ensure safety in the workplace and to minimize or eliminate occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, “Occupational Exposure to Bloodborne Pathogens.”

##  Universal Precautions:

### Universal precautions apply to blood and other body fluids containing visible blood. Universal precautions also apply to tissues and to the following fluids: cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Universal precautions also apply to semen and vaginal secretions, tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid.

### Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus, saliva and breast milk unless they contain visible blood.

### Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infective materials. In addition, under universal precautions, it is recommended that all health care workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices.

### The objective of the OSHA Standard on Bloodborne Pathogens is to limit exposure to blood and other potentially infectious materials. Exposure could result in the transmission of disease. The purpose of this Plan is to assist the Laboratory in implementing and ensuring compliance with the Standard, thereby protecting all employees. This Plan includes:

#### Determination of employee exposure

#### Methods of implementation and control

#### Procedures for evaluating circumstances surrounding an exposure incident

#### Post-exposure evaluation and follow-up

#### Recordkeeping

#### Education and training requirements

#### Hepatitis B vaccination

## Program Administration

### The Laboratory Director and/or his designee are responsible for the implementation of the Exposure Control Plan. The Director and/or his designee will maintain, review, and update the Plan at least annually, and whenever necessary, include new or modified tasks and procedures. The Supervisors are responsible for exposure control, appropriate orientation, and training for all employees in their respective areas.

### Those employees who are determined to be at risk for occupational exposure to blood or body fluids must comply with the established procedures and work practices outlined in this Plan.

### Personal protective equipment, engineering controls, labels, and red bags as required by the Standard will be provided for and maintained by the Laboratory.

## Determination of Employee Exposure

### All employees working in the laboratory routinely perform tasks that involve processing or handling human blood, body fluids, tissue or organs; or processing or handling of equipment, materials, or waste that may have been contaminated with human blood, body fluids or other potentially infectious material (PIM) as defined below are deemed at “high risk.” Other employees are at “low risk” depending on how much contact they have with the laboratory.

### *Other Potentially Infectious Materials*: Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and HIV-containing cell or tissue cultures, organ culture medium or other solutions; and blood, organs, or other tissue from experimental animals infected with HIV or HBV.

### All employees identified as having occupational exposure potential must comply with all provisions of the ECP.

## Methods of Implementation and Control

### Department heads, managers, and supervisors are responsible for ensuring compliance and monitoring adherence to this safety policy. Specifically, they must ensure that all personnel working under their supervision:

#### Understands and comply with practices/procedures identified in the ECP and other relevant safety procedures;

#### Have access to appropriate and necessary personal protective equipment and

#### Receive training, as required by this ECP.

### Failure to comply with this policy will be managed as a work rule violation through the disciplinary actions.

### All employees covered by the bloodborne pathogen standard will receive information about bloodborne pathogens through educational video and handout during their initial orientation. An annual review will also be conducted. A copy of the Plan is available to all employees at all times.

### The Plan will be reviewed and updated annually by the Medical Director or designee. More frequent review and revision will be conducted as needed to reflect changes in the regulations or work conditions.

### Engineering, housekeeping and work practice controls will be used to prevent or minimize exposure to blood borne pathogens. Examples of such controls are as follows:

#### Facilities for hand washing are available.

#### Specimen containers are leak-proof, puncture resistant, color-coded or labeled with a biohazard warning label.

#### Sharps containers are available in areas where sharps are used.

#### Personal protective equipment such as gloves, impervious gowns and/or aprons, goggles, are provided for appropriate use.

#### Minimal splashing, spraying or splattering is observed when performing a procedure.

#### Splashguard screens and ventilating laboratory hoods are available in areas where needed.

#### Cleansers and disinfectants are available for cleaning contaminated areas.

#### Food and beverages are not to be kept in refrigerators or counters where blood or potentially infectious material is processed.

#### Smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses is prohibited where there is any likelihood of exposure to blood and other infectious materials. A lunchroom provided by the company.

#### Biohazard labeled waste containers and red bags are provided for disposal of blood and potentially infectious materials.

## Personal Protective Equipment-General Guidelines

### Disposable, single-use latex or nitrile gloves shall be worn where it is reasonably anticipated that GENETWORx Personnel will have hand contact with blood or other potentially infectious materials, when collecting and processing human specimens and when handling or touching contaminated items or surfaces. Disposable gloves are not to be washed or decontaminated for reuse and are to be placed as soon as practical when they become contaminated or as soon as feasible if they are not torn or punctured, or when their ability to function as a barrier is compromised.

### Disposable protective clothing must be worn when there is a risk of body fluids spattering or becoming aerosolized and contacting and individual’s skin or clothing.

### Face shields or masks in combination with eye protection such as goggles or glasses with solid side shield are required to be worn when splashes, sprays, aerosolized blood, or other potentially infectious materials may contact eye, nose, mouth, or mucous membranes.

### All Personal Protective Equipment shall be removed prior to leaving the work area. When PPE is removed, it shall be placed in an appropriately designated container for storage, washing, decontamination, or disposal.

### After the removal of personal protective gloves, GENETWORx personnel shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and running tap water for at least ten seconds (see attached documentation for general guidance).

### All areas of the worksite must be maintained in a clean and sanitary condition. All tables must be disinfected with an appropriate disinfectant solution at least daily and immediately following completion of procedures involving human blood and other potentially infectious materials.

### The Laboratory will identify the need for changes in the Plan by reviewing the OSHA standards, new federal or state regulations and guidelines, review of occurrence and ‘near miss’ reports, employee interviews, and safety surveys. All staff members are encouraged to participate in making the Laboratory a safe workplace and reduce exposure to bloodborne pathogens.

## Gloving, gowning, masking, and other protective barriers as part of universal precautions:

### All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure during contact with any patient's blood or body fluids that require universal precautions.

### **Gloves**. Gloves must be worn:

#### For touching blood and body fluids requiring universal precautions, mucous membranes, or nonintact skin of all patients, and

#### For handling items or surfaces soiled with blood or body fluids to which universal precautions apply.

#### For all phlebotomy procedures including for performing finger and/or heel sticks on infants and children and during phlebotomy training.

### Gloving guidelines

#### Use sterile gloves for procedures involving contact with normally sterile areas of the body.

#### Use examination gloves for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves.

#### Change gloves between patient contacts.

#### Do not wash or disinfect surgical or examination gloves for reuse. Washing with surfactants may cause "wicking," i.e., the enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration.

#### Use general-purpose utility gloves (e.g., rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration. Regular latex-free gloves may be used as well, but must be discarded when first removed and must not be reused.

#### Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately or as soon as patient safety permits if contaminated with blood or body fluids requiring universal precautions. Hands should be washed immediately after gloves are removed.

#### Note that the Center for Devices and Radiological Health, Food and Drug Administration (FDA), has responsibility for regulating the medical glove industry. For more information about selection of gloves, refer to section VI Glove Use Policy.

#### **Face Protection**: Masks and protective eyewear or face shields should be worn by health care workers to prevent exposure of mucous membranes of the mouth, nose, and eyes during procedures that are likely to generate droplets of blood or body fluids requiring universal precautions.

#### **Gowns**: Gowns, laboratory coats and/or aprons should be worn during procedures that are likely to generate splashes of blood or body fluids requiring universal precautions.

#### **Handling of Sharps:** All health care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped by hand, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal. The puncture-resistant containers should be located as close as practical to the use area. All reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.

#### **General infection control practices** should further minimize the already minute risk for salivary transmission of HIV. These infection control practices include the use of gloves for digital examination of mucous membranes and endotracheal suctioning, handwashing after exposure to saliva, and minimizing the need for emergency mouth-to-mouth resuscitation by making mouthpieces and other ventilation devices available for use in areas where the need for resuscitation is predictable.

#### Although universal precautions do not apply to human breast milk, gloves may be worn by health care workers in situations where exposures to breast milk might be frequent, e.g., in breast milk banking.

## Waste Management

Universal precautions are not intended to change waste management programs previously recommended by CDC for health-care settings (1). Policies for defining, collecting, storing, decontaminating, and disposing of infective waste are generally determined by institutions in accordance with state and local regulations. Information regarding waste management regulations in health-care settings may be obtained from state or local health departments or agencies responsible for waste management. Reported by: Center for Devices and Radiological Health, Food and Drug Administration. Hospital Infections Program, AIDS Program, and Hepatitis Br, Div of Viral Diseases, Center for Infectious Diseases, National Institute for Occupational Safety and Health, CDC.

## Other General Guidelines

### Aerosols:

#### "Popping corks off vacutainer tubes creates infectious aerosols. Caps should be removed gently using gauze or Kimwipes. Dispose of the gauze in designated biohazard bags.

#### Following the ejecting of fluid specimens from a syringe, insert the syringe into a marked sharps container. Keep all specimens covered with caps or parafilm when not being utilized.

#### Waste or Sharps containers should not be overfilled or allowed to spill over.

#### Procedures and manipulations of potentially infectious material are to be performed in such a way as to minimize formation of droplets and aerosols.

### Accident reporting: See, Section IX, Reporting of Occupational Injuries or illnesses and Quality Manual Attachment 15, Documentation of Laboratory Accidents.

### Biohazard hoods: Biological safety cabinets (Class II) or other containment devices are to be used for procedures with high potential for creating aerosols or infectious droplets.

### Centrifugation:

#### The top of the centrifuge should always be closed when the unit is in motion.

#### Tubes to be centrifuged should be covered with cap, stopper or parafilm to prevent aerosols.

#### Each employee using the centrifuge is responsible for cleaning up spills/broken glass, etc. at the end of the procedure. (See spill procedure, Section IV).

### Clothing:

#### Impervious laboratory coats are to be worn while working with potentially infectious material (see above) and are to be removed or discarded before leaving the laboratory, when entering the lounge, or when using the restroom.

### Food storage, smoking, eating, drinking, and cosmetics:

### Food storage, smoking, eating, drinking and application of cosmetics (including lip balm) are prohibited in the laboratory.

### Hand washing:

#### Wash hands between each patient from whom you draw blood with an effective anti-microbial method.

#### Wash hands frequently in the lab itself, even if gloves were used.

#### Wash hands prior to eating, drinking or answering the telephone. Biohazard marked phones must be answered while wearing gloves.

#### Always wash hands after contact with patients or specimens even with glove use.

#### Figure 1 demonstrates effective handwashing technique using antimicrobial soaps

|  |
| --- |
| A close up of a logo  Description generated with high confidence |
|  |

### Housekeeping: Laboratory work surfaces should be decontaminated with a disinfectant in general on completion of work if contamination is suspected, immediately after spills, and more frequently if necessary.

### Labeling: All specimens should be regarded as potentially infectious. Therefore, personnel should always use Universal Precautions when handling all specimens. No special labeling is required with the exception of specimens in chemical fixatives such as formalin.

### Laboratory requisitions:

#### Visibly contaminated lab requisitions will not be accepted.

#### Specimen requisitions should be inspected for contamination at the time of specimen pick-up or delivery.

#### Contaminated requisitions and specimen will be returned with a request for a clean requisition.

### Needles, syringes, sharps:

Needles, glass slides, syringes and other disposable sharps are to be discarded in puncture resistant containers designed solely for that purpose. Needles are not to be purposely bent, cut, recapped, broken, removed from disposable syringes, reinserted into the original sheath or manipulated in any other way.

### Pipetting:

#### Mechanical pipetting devices are to be used for the manipulation of all liquids in the laboratory.

#### Mouth pipetting is not allowed.

#### Pipette all reagents and specimens using a rubber bulb or other safety device.

#### Discard used pipettes or capillary tubes in suitable disinfectants or waste containers.

### Re-usable items to be sterilized: Pipettes, glass slide plates and glassware used for patient specimens must be soaked in disinfectant for six hours or autoclaved and then cleaned with detergent and rinsed with clean water.

### Specimen disposal:

#### All patient specimens that are to be discarded must be placed into white, biohazard waste bags, tied securely. Housekeeping will collect the bags and take them for incineration.

#### The waste bags will be placed into a secure, portable transport cart, with secure lid for transport to the incinerator.

#### All laboratory waste is considered to be possibly infectious and will be placed in the white biohazard waste bags.

### Use of microbiological hoods: Hoods should be used as much as possible to decrease exposure to infectious agents. Hoods must be used with specimens known to be contaminated with the hepatitis, tuberculosis or aids viruses.

## Procedures for Evaluating Circumstances Surrounding an Exposure Incident

### Policy: All employees should notify the Medical Director and/or his designee when an incident of exposure or possible exposure occurs. The Medical Director and/or his designee will evaluate the reported incident and determine risk. A record of such reports and findings is maintained in a designated Laboratory file.

### The Exposure Incident Should be documented on Quality Manual Attachment 15. Reporting of Occupational injuries

### Employees can request his/her own exposure record at anytime. Such record can also be released to anyone having written consent of the employee within 15 working days. Such requests should be sent to the Medical Director or his designee.

###  Post-Exposure Evaluation and Follow-Up

#### Information surrounding the exposure incident will be obtained from the at-risk employee. Items that need to be addressed include engineering controls and work practices at the time, the device used, protective equipment used and worn at the time of exposure, location of the incident, procedure being performed at the time of incident, and employee’s training.

#### Records of post-exposure follow-up and treatment, if applicable, is kept in the designated Laboratory file.

## Recordkeeping

### Records of exposure, follow-up, and training are kept for each employee. Training records are kept for at least three years. Records of exposure and follow-up are kept for at least the duration of the employment plus 30 years, or as required by law.

## Education and Training Requirements

### All employees who are at risk for occupational exposure to bloodborne pathogens will receive training during orientation by their respective Supervisor. The training will consist of videotape program, handout, and personal instruction as needed.

### Training will include the following:

#### An explanation of the OSHA standard for Bloodborne Pathogens

#### Epidemiology and symptomatology of bloodborne disease

#### Modes of transmission of bloodborne pathogens

#### What constitutes an exposure incident

#### Control measures used at the facility to control and minimize exposures

#### Personal protective equipment available at the facility

#### How to dispose of contaminated materials

#### What to do in case of exposure and the importance of early reporting

#### Post-exposure follow-up and evaluation

#### Signs and labels used at this facility

#### Hepatitis B vaccination program

### Refresher training is required annually. Training in new products or devices is provided.

## Hepatitis B Vaccination

### Hepatitis B vaccination is offered by the Laboratory for all employees.

### Employees who are at risk for exposure to bloodborne pathogens or other potentially infectious materials are offered Hepatitis B vaccine at no cost. The vaccine is administered at a doctor’s office. Vaccination is encouraged unless: (1) documentation exists that the employee has previously received the series; (2) antibody testing reveals that the employee is immune; (3) medical evaluation shows that vaccination is contraindicated.

### If the employee declines vaccination, he/she must sign a declination form. Employees who decline vaccination may request and obtain the vaccine at a later date at no cost. Documentation of refusal is kept in the Employee’s file.

## Compliance Monitoring

### The Standard requires employers to ensure that employees comply with the protective measure as outlined. Methods of compliance monitoring include but are not limited to: the direct observation of performance, review of safety minutes, review of occurrence reports, informal reports or concerns expressed by the staff, and comments received during evaluation, education and training sessions.

# Fire Safety Policy

## Purpose:

To provide a plan for the orderly evacuation of GENETWORx Employees and to establish the necessary procedures for fire emergencies.

## Designated roles and responsibilities:

### The Safety Committee is responsible for

#### seeing that the Fire Safety Plan is implemented. The Laboratory Director is a chair of Safety Committee, and he/she is responsible for ensuring the implementation of this plan. Chief Laboratory Officer will work very closely with Chief Operations Officer and Fire Department to ensure safety of all GENETWORx Employees. Please see Appendix D for a complete list of Safety Committee Members. To assess all the Safety Committee Activities, please refer to Safety Committee Minutes.

#### Designated Safety Committee members will assist in the implementation of this plan by knowing and communicating evacuation routes to occupants during emergency evacuation and report the status of the evacuation to the Safety Committee for assessment and necessary improvements.

### Managers/Supervisors are responsible for:

#### Reviewing the evacuation plan with employees in their area within 30 days of employment

#### Notifying the employees to evacuate upon hearing the fire alarm, or seeing smoke or fire

#### Closing doors to their immediate area upon evacuating if applicable (do not lock the doors)

#### Assembling at designated point outside of building and account for all immediate employees in their area

#### Report any missing personnel ASAP to the Safety Committee member, Chief Laboratory Officer, or Chief Operation Officer

### Responsibilities of all other employees:

#### To know where nearest fire extinguisher is located

#### To know potential fire hazards in your immediate work environment

#### Evacuate building using closest exit

#### Report to the designated point outside of the building

#### Perform other duties at the request of their Supervisor/Manager

## Preparation and planning for emergencies:

### Pre-planning for emergencies is a crucial element of this plan. The following steps have been taken in planning for emergency evacuation of this building:

#### All exits are labeled and operable.

#### Evacuation route diagrams have been approved by GENETWORx CEO and are posted on all floors and at all exits, elevator lobbies, and major building junctions.

#### Occupants do not block exits, hoses, extinguishers, corridors or stairs by storage or rearrangement of furniture or equipment. Good housekeeping is everyone's responsibility.

#### All Safety Committee Members have been trained in their specific duties and all building occupants have been instructed in what to do in case of an emergency evacuation.

#### Fire evacuation drills are held at least annually in this building and are critiqued and documented. Safety Committee Members will analyze and make suggestion for any improvement if necessary.

#### Appendix A contains floor plan for each floor that are posted and/or used in instructing employees and visitors using this building's facilities.

## Evacuation Procedure:

### Anyone who receives information or observes an emergency situation should immediately call 911.

### In this building, occupants will be notified of emergencies by fire alarm.

### Remember: **RACE**

#### R – Rescue

#### A – Alarm

#### C – Contain

#### E – Extinguish or Evacuate

### Occupants will**:**

#### Know at least two exits from the building.

#### Be familiar with the evacuation routes posted on the diagram on your floor.

#### To report a fire or emergency, call 911. Give your name and the floor that locates the fire. State exactly what is burning, or what is smoking or what smells like a fire to you. Then notify the Chief Laboratory Officer or Chief Operation Officer (or other designated person) and activate the building notification system.

#### When notified to evacuate, do so in a calm and orderly fashion:

### Important Notes

#### Walk, don't run

#### keep conversation level down

#### take your valuables and outer garments if you have time

#### close all doors behind you

#### use the stairs, not the elevators

#### assist others in need of assistance

### Go to the designated assembly area or as instructed during the notification. If exiting the building, move at least 150 feet from the building to allow others to also safely exit the building. Report to you Manager outside of the building to assist your Supervisor/Manager in making sure that everyone is accounted for.

### Persons with Disabilities (mobility, hearing, sight): Everyone who requires assistance to-evacuate is responsible for pre-arranging with someone else in their immediate work area to assist them (See below).

## Responsibilities During Evacuation

### Safety Officer

#### **NOTE**: The Safety officer will assume responsibility for the following. Note that if the Safety Officer is not present responsibility will be delegated in the following order:

##### Laboratory Manager

##### First Manager or Supervisor on the Scene

##### First Lead Tech or Charge tech

#### Determine the need for evacuation based on information provided by Safety and Security. This will be made in conjunction with the Laboratory Supervisors.

#### Check to be sure all personnel and patients have been evacuated (including those who may have a disability and need assistance in evacuating the laboratory) using Attachment 21 Fire Drill review form.

#### Close doors and windows.

#### Shut down all gas equipment.

#### Conduct orderly evacuation.

#### Assemble employees near the designated area

#### Take attendance and report missing staff to the Safety Officer or designee

## Special Needs of Persons with Disabilities

### No one is expected to endanger him/herself to effect or assist with evacuation of others, but everyone has a duty to ensure that other occupants are aware of an emergency. Similarly, it is expected that individuals will aid anyone requiring assistance to safely evacuate.

### Persons with disabilities may not be readily identifiable to others. Anyone with a disability not clear and not made known to management (see below) should inform the Safety Officer and/or a supervisor when an evacuation is ordered in order to receive assistance in the event of an emergency.When assistance arrangements are made, there is no requirement to make them public.

### Assistance Arrangements

#### New or existing employees who have a disability should notify the Human Resources as soon as possible. In most cases this will be made known to the Laboratory Manager by Human Resources.

#### The Laboratory Manager, in conjunction with the employee’s supervisor, will assign an escort and an alternate escort to the employee. These escorts will be on the same shift as the disabled employee.

#### The assigned escorts will assist the disabled employee to evacuate the laboratory.

#### Should the assigned escorts not be present during the disabled employee’s shift, the employee must notify the supervisor, or charge tech, who will assign a temporary escort to assist the employee in case of an emergency evacuation.

### Assistance Guidelines

#### Individuals with Mobility Limitations

##### Evacuation of these persons during an emergency is of concern as most elevators will not operate (should not be used) during a fire alarm. If there is no immediate danger (obvious smoke or fire), these persons should either stay in place with their escorts or be moved to a fire-rated stairwell until emergency personnel determine the nature of the situation. Officials may decide that no evacuation is necessary, they may remove the person using the elevator with an override key, or they may carry the person out of the building.

#### Individuals with Vision Impairments

##### Most persons with vision limitations will be familiar with the immediate area they are in. In the event of an emergency, tell the individual how and where to exit. Have the person take your elbow and escort him or her (this is the preferred method when acting as a "sighted guide"). As you walk, tell the person where you are and advise him or her of any obstacles. When you reach safety, orient the person to where he or she is and ask if any further assistance is needed.

#### Individuals with Hearing Impairments

##### Since persons with impaired hearing may not perceive audio emergency alarms, an alternative warning technique is required. Two methods of warning are:

##### 1. Write a note telling what the emergency is and the nearest evacuation route. (Example: "Fire--go out rear door to right and down. **Now**!")

##### 2. Turn the light switch on and off to gain attention, and then indicate through gestures or in writing what is happening and what to do.

It may be prudent to escort the person with a hearing impairment as you leave the building.

## Fire evacuation drills:

All building occupants must be familiar with what they should do during an evacuation. The most effective method of familiarizing them is to hold a fire drill at least annually. Holding a fire drill has other advantages as well; it will provide you with an opportunity to evaluate your notification and evacuation procedures and it will give you an opportunity to test your fire alarm system and make occupants aware of the sound.

Steps In Conducting a Fire Drill:

### If you have an alarm system you must first contact the building manager to make the appropriate arrangements.

### Contact the Fire Marshal before holding your drill so that a representative can be on site to assist in critiquing the evacuation.

### Although the fire drills should be unannounced, you may need to give advanced notice to key personnel in your building.

## The Fire Quadrangle:

This information is provided for the employees to better understand how fire extinguishers work.

Four factors should be present at the same time for fire to occur:

### Enough oxygen to sustain combustion

### Enough heat to raise the material to its ignition temperature

### Some sort of fuel or combustive material

### The chemical, or exothermic reaction that is fire

Oxygen, heat, and fuel are frequently referred to as the "fire triangle." The important thing to remember is: take any of these components away, and you will not have a fire or the fire will be extinguished.

Essentially, fire extinguishers put out fire by eliminating one or more elements of the fire triangle.

The main principle of Fire safety is based upon keeping fuel sources and ignition sources separate.


## Classification of fuels:

### *CLASS A: wood, paper, cloth, trash, plastics*: Solid Combustible materials that are not metals ( Class **A** fires most of the times leave an **A**sh)

### *CLASS B: flammable liquids* - gasoline, oil, grease, acetone, also flammable gases (Class **B** fires most of the time involve materials that **B**oil or **B**ubble)

### *CLASS C: electrical equipment* (Class **C** fires mostly deal with electrical **C**urrent)

### *CLASS D: metals*

## Fire Extinguishers:

### Introduction: Most fire extinguishers will have a pictograph label informing you which classifications of fire the extinguisher is designed to fight.

### Water (APW) Extinguishers

#### **Never use water to extinguish flammable liquid fires.** Water is extremely ineffective at extinguishing this type of fire, and you may, in fact, spread the fire if you try to use water on it.

#### **Never use water to extinguish an electrical fire**. Water is a good conductor, and there is some concern for electrocution if you were to use water to extinguish an electrical fire. Electrical equipment must be unplugged and/or de-energized before using a water extinguisher on it. APWs extinguish fire by taking away the "heat" element of the fire triangle.

### Carbon Dioxide Extinguishers:

#### Carbon Dioxide extinguishers are filled with non-flammable carbon dioxide gas under extreme pressure. You can recognize a CO2 extinguisher by its hard horn and lack of pressure gauge. The pressure in the cylinder is so great that when you use one of these extinguishers, bits of dry ice may shoot out the horn.

#### CO2 cylinders are red and range in size from 5 lbs to 100 lbs or larger. In the larger sizes, the hard horn will be located on the end of a long, flexible hose.

#### **CO2s are designed for Class B and C (flammable liquid and electrical) fires only.**

#### Carbon Dioxide is a non-flammable gas that extinguishes fire by displacing oxygen, or taking away the oxygen element of the fire triangle. The carbon dioxide is also very cold as it comes out of the extinguisher, so it cools the fuel as well. **CO2s may be ineffective at extinguishing Class A fires** because they may not be able to displace enough oxygen to successfully put the fire out. Class A materials may also smolder and re-ignite.

#### **All CO2 extinguishers undergo hydrostatic testing and recharge every five years.**

### Dry chemical Extinguishers:

#### Dry Chemical Extinguishers come in a variety of types. You may see them labeled:

#### "**DC**" short for "dry chem"

#### "**ABC**" indicating that they are designed to extinguish class A, B, and C fires, or

#### "**BC**" indicating that they are designed to extinguish class B and C fires.

### ABC extinguishers are red and range in size from 5 lbs to 20 lbs on campus.

### **It is extremely important to identify which types of dry chemical extinguishers are located in your area.**

### Dry chemical extinguishers put out fire by coating the fuel with a thin layer of dust, separating the fuel from the oxygen in the air. The powder also works to interrupt the chemical reaction of fire, so these extinguishers are extremely effective at putting out fire.

## Rules for Fighting Fires:

Fires can be very dangerous and you should always be certain that you will not endanger yourself or others when attempting to put out a fire. For this reason, when a fire is discovered:

### Assist any person in immediate danger to safety, if it can be accomplished without risk to yourself.

### Activate the building fire alarm system or notify the fire department by dialing 911 (or designating someone else to notify them for you). When you activate the building fire alarm system, it will automatically notify the fire department and get help on the way. It will also sound the building alarms to notify other occupants, and it will shut down the air handling units to prevent the spread of smoke throughout the building.

### Only after having done these two things, if the fire is small, you may attempt to use an extinguisher to put it out.

### **Know what is burning.** If you don't know what is burning, you don't know what type of extinguisher to use. Even if you have an ABC extinguisher, there may be something in the fire that is going to explode or produce highly toxic smoke. Chances are, you *will* know what's burning, or at least have a pretty good idea, but if you don't, let the fire department handle it.

### **The fire is spreading rapidly beyond the spot where it started.** The time to use an extinguisher is in the incipient, or beginning, stages of a fire. If the fire is already spreading quickly, it is best to simply evacuate the building, closing doors and windows behind you as you leave.

### Do not Fight Fire if:

#### **You don't have adequate or appropriate equipment.** If you don't have the correct type or large enough extinguisher, it is best not to try to fight the fire.

#### **You might inhale toxic smoke.** If the fire is producing large amounts of smoke that you would have to breathe to fight it, it is best not to try. Any sort of combustion will produce some amount of carbon monoxide, but when synthetic materials such as the nylon in carpeting or foam padding in a sofa burn, they can produce highly toxic gases such as hydrogen cyanide, acrolein, and ammonia in addition to carbon monoxide. These gases can be fatal in very small amounts.

#### **Your instincts tell you not to.** If you are uncomfortable with the situation for any reason, just let the fire department do their job.

#### **The final rule is to always position yourself with an exit or means of escape at your back before you attempt to use an extinguisher to put out a fire.** In case the extinguisher malfunctions, or something unexpected happens, you need to be able to get out quickly, and you don't want to become trapped. At any time you need to remember, **always keep an exit at your back.**

## How to use a fire extinguisher:

Remember **PASS**:

### **P: Pull** the pin on the top of the extinguisher – this will allow you to discharge the extinguisher

### **A: Aim** at the **base** of the fire – if you will aim at the flames, there is a possibility that flames will “fly” and spread fire around

### **S: Squeeze** the top handle – this action will press a button that releases extinguishing agent under pressure

###  **S: Sweep** from side to side until the fire is completely out. Start extinguishing the fire from a safe distance moving slowly towards the fire as you extinguishing it.

Please see Appendix A for all the fire maps.

Please see Appendix B for Fire Drill Evaluation Form.

Please see Appendix C for Fire Safety Quiz.

Please see Appendix D for a complete list of Safety Committee Members.

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Safety Committee Members (as of July 2015)

**Any further changes in the membership will be noted and a new list of Safety Committee Members will be printed.**

* Laboratory Director
* Director of Operations
* Safety Officer
* Chief Executive Officer

# Biohazard Waste Disposal

## Purpose:

To ensure that all infectious wastes (e.g., glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded in accordance with Federal, State and local regulations.

##  Biohazard containers should

### Be prominently marked biohazard

### Bear the universal biohazard symbol

### Be of the universal color, orange, or orange and black, or red.

### Be leak proof and puncture-resistant.

### Be used for all blood, body fluids, and tissues, and disposable materials contaminated with them.

### Have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and/or disposal.

### The total weight of the biohazard containers should not exceed 40 lbs.

## Equipment:

### Red biohazard bags

### Red biohazard containers

### Chemical waste collection barrels

### Lab Coats

### Gloves

### Goggles

### Splash Shield

## General Disposal

### Specimen vials are disposed of into red biohazard containers labeled specimens only.

### At the end of each day the biohazard bags containing the specimens are collected and the date is put on the container.

### The bags are collected into a biohazard box and labeled for pick up. The specimens are retained for two weeks after the date received.

### All other biohazard trash is collected into red bags, packaged in a biohazard box and is available for immediate pick up.

### All solid biohazard waste is picked up and disposed of by an authorized company.

### All chemical waste is disposed of into hazardous chemical waste barrels. These barrels are picked up as needed by chemical waste disposal company.

### Proper PPE should be worn when dealing with any biohazard or chemical waste. See Section VI of this Policy.

## Sharps Disposal

**Procedure 2:** Perform this procedure per the following steps for all sharps disposal.

### Upon completion of usage of all sharps (Note 1), activate safety device, as applicable.

### Place all sharps in a red sharps puncture-resistant container.

### Do not fill the sharps container above the indicated fill line.

### When full, cap the top of the container with the attached lid.

### Place the container in the hallway for removal and incineration removal by contracted company.

### All slides and/or coverslips, broken or intact, that will not be used for a diagnosis, microtome blades and scalpel blades must be disposed of in a red BioHazard Sharps Box (punch resistant). When the sharps container is ¾ full, it must be closed and taped up.

### An authorized contracted vendor, such as Secure Waste will remove the container on the next scheduled pick-up.

|  |  |
| --- | --- |
| Note | Notes |
| **1** | Sharps may include, but are not limited to the following: sterile syringes, needles, lancets, other blood-letting devices, etc, which are capable of transmitting infection. |
| **2** | Under US law, shearing or breaking of contaminated sharps is prohibited. Bending, recapping, or removing contaminated needles is prohibited. Needles are expected to be used (only once) and immediately discarded, un-recapped, into accessible sharps containers. |

# Emergency Notification Protocol

## Purpose:

### The purpose of this protocol is to establish a list of people to notify in case of an emergency in the lab.

## Procedure:

### In the event of an emergency that results in serious injury to laboratory staff, damage to property, or serious disruption of laboratory operations, follow emergency notifications and response and initiate notification of laboratory personnel and management.

### Notification Order:

#### Laboratory Director

#### Chief Laboratory Officer

#### Supervisor

#### Lead Technologist

### It is a responsibility of a Laboratory Supervisor to ensure that all of the phone numbers of the Supervisor and employees are exchanged so all of the appropriate personnel can be notified.

### Chemical Spill:

### In case of chemical spill, you will need to post a sign outside the laboratory warning those who may enter of the hazard.

### Emergency

### In case of emergency or fire please call 911 immediately!

### In case of emergency also please contact immediately:

### Bill Miller, CEO: cell (804) 517-1028

# Documentation of Laboratory Incidents resulting in property damage

## Process:

The reporting of laboratory accidents resulting in property damage process is described in the table below

|  |  |
| --- | --- |
| Who is Responsible | What Happens |
|  Employee | Report the incident immediately to a supervisor  |
| Supervisor | Write a narrative statement describing the incident to include date, time, witnesses, and other participants, as necessary. |
| Supervisor | The supervisor has the affected employee sign the statement with the supervisor as a witness  |
| Supervisor | The supervisor makes a copy of the incident statement. The original statement will be forwarded to the Laboratory Director. who will consult with Human Resources as well as any other department affected to see if further investigation is warranted and any damages need to be assessed against the employee |
| Laboratory Manager | Consults with Human Resources as well as any other department affected to see if further investigation is warranted and any damages need to be assessed against the employee |
| Lab Safety Committee | The incident will be reviewed by the Laboratory Safety Committee and follow-up action taken as necessary to include forwarding to senior management |

# Laboratory Corrective Action Reports

## Purpose:

To insure a compliance with existing SOP’s, record any deviations from good laboratory practices; and provide traceable Quality Control/Quality Assurance records.

## Responsibility:

Laboratory personnel, Accessioning personnel, Client Services personnel.

It is Laboratory personnel’s responsibility to issue a discrepancy report or an Incident report in case of any deviation from our current SOP’s. Supervisor or Manager of each Laboratory section must make sure that appropriate report is filed when there is a deviation. All Laboratory Corrective Action Reports need to be signed by Laboratory Director. Copies of all Discrepancy Reports should be delivered to Client Services to make sure that appropriate corrective action was taken.

## Procedures:

### Notification of Specimen Discrepancy:

### During initials steps of specimen processing, like Accessioning and Grossing, if there is any discrepancy noted with the specimen, Notification of Specimen Discrepancy must be issued. That notification states that GENETWORx received a specimen indicated in the report that GENETWORx unable to process without additional information provided to our office. Please see attached form.

### In the discrepancy report we provide minimal patient information, accession number, date specimen was received and type of the discrepancy. One copy of the Notification of Specimen Discrepancy is kept in the Laboratory, and one copy is given to Client Services. Client Services contacts the Physician’s office to get additional information, so we can process the patient’s tissue according to our SOP’s. It is a responsibility of Client Services to recognize the accounts that will need additional training to run more efficiently and provide better patient care.

### Notifications of Specimen Discrepancy will become a part of the laboratory Quality Assurance/Quality Control Program for us to be able to provide a better patient care. The number of Discrepancy reports and main problems with received specimens will be discussed and noted in the Quarterly Quality Improvement Meetings Minutes.

### Laboratory Corrective Action Report: (Refer to Quality Manual QP 500 Quality Control )

In the event on any deviation from Laboratory SOP’s, Lead Tech, Supervisor, or Laboratory Manager needs to issue a Laboratory Incident Report. That report should provide the date of the incident; type of incident; description and resolution of incident; and steps that will be taken to avoid this type of incident in the future. Please see attached form.

### All Laboratory Incident Reports should be reviewed and signed by Laboratory Director of GENETWORx. All the Incident Reports are kept in the Laboratory. This documentation becomes a part of the Laboratory Quality Assurance/Quality Control Program to provide a better patient care in the future. The number of Incident reports and Type of Incidents will be discussed and noted in the Quarterly Improvement Meetings Minutes.

# Liquid Nitrogen/Dry Ice Policy

## GENETWORx does not currently use liquid nitrogen at its facility.

## Dry Ice Policy

### Personal Protection Equipment (PPE)

#### The use of insulated gloves, dry ice tongs or scoop, and safety goggles/glasses is mandatory when handling dry ice.

### Storage and use of all containers of dry ice should only be in well-ventilated areas. Do not use or store dry ice confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A CO2 leak in such an area could cause an oxygen-deficient atmosphere.

### A Safety Data Sheet must be available to personnel

### All staff should be trained on the safe handling of dry ice.

# UV Policy

## Policy Statement

It is the policy of GENETWORx to insure that all personnel are protected adequately from UV radiation exposure.

## Reason for Policy/Purpose

### The hazards of UV light from sunlight are well publicized. However, UV light sources are also found in the workplace, including labs, mechanical rooms, and shops. Sources include BSCs, certain types of handheld light sources, transilluminators, crosslinkers, and laboratory instruments such as spectrophotometers. According to the Health Physics Society: “Accidental UV overexposure can injure unaware victims due to the fact UV [light] is invisible and does not produce an immediate reaction.… Reported UV accident scenarios often involve work near UV [light] sources with protective coverings removed, cracked, or fallen off. Depending on the intensity of the UV [light] source and length of exposure, an accident victim may end up with a lost-time injury even though totally unaware of the hazardous condition.”(1)

### UV germicidal lamps, such as in BSCs and HVAC air handlers, are designed to emit UV-C radiation because of its ability to kill bacteria and molds. Welding operations associated with maintenance activities also produce UV-C. Overexposure to UV-C can cause corneal burns, commonly termed welder’s flash.

### UV burns to the eye are often described as a “sand in the eye” feeling and are often reported to be very painful. One should never work in a BSC with the UV lamps on, and the UV lamps should not be on when the room is occupied.

## Policy/Procedures

### Access to rooms with open source transilluminators and post a warning sign indicating face should be controlled and other skin protection is needed to enter when a transilluminator is in use. The protection required is standard laboratory apparel including a fully buttoned lab coat, gloves, long pants, and closed-toe shoes. In addition to the standard lab attire, a polycarbonate face shield labeled for UV protection (as opposed to just glasses/goggles) is needed to protect the eyes and face and prevent facial burns. In addition, lab workers should take care to prevent gaps in clothing that will expose the skin, such as around the neck and wrists.

### Safety glasses that protect from laboratory-generated UV radiation must be stamped with ANSI Z87.1. It is important to note that polycarbonate safety glasses will not protect from high-radiant UV energy sources such as torch cutting, welding, or lasers. Specialized safety glasses are required for safe operation of these devices.

### Another warning: there are many common medications that increase an individual’s photosensitivity and a resultant susceptibility to UV-related burns. Review all your medications with your pharmacist or physician to determine whether any increased risk for UV-induced damage is associated with your medication.

### Transilluminators or UV light boxes are used for visualization of DNA on gels. They typically look like flat boxes with glass tops and UV lamps inside. The glass top allows the light to shine on the gel, causing the DNA to “glow,” which potentially exposes the user. To reduce risk of injury, most models today come equipped with a shield to block the UV light. For older models, install after-market shields rated for UV light to provide protection. Check the UV shields/cover regularly for cracks or other damage.

### In the United States, occupational exposure guidelines for UV radiation have been established by the American Conference of Governmental Industrial Hygienists.(2) Handheld meters for measuring UV radiation are commercially available, but expert advice from a qualified industrial hygienist or health physicist is recommended to ensure selection of the correct detector and diffuser for the UV wavelengths emitted by the source.

### Any instruments that may emit UV light should have posted signs warning of the exposure.

e.g Warning: This device produces potentially harmful ultraviolet (UV) light. Protect eyes and skin from exposure.

References

1. Ultraviolet Radiation, Gary Zeman, Health Physics Society, MacLean, VA. August 2011 <http://hps.org/hpspublications/articles/uv.html>

2. Threshold Limit Values and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, Cincinnati, OH. 2011 <http://www.acgih.org/>

# Ergonomics Policy

## Policy Statement:

It is the policy of GENETWORx to improve the comfort and well-being of employees by identifying and correcting ergonomic risk factors in the workplace. The company’s Ergonomic Program was developed to effectively identify and prevent work-related musculoskeletal disorders through engineering, equipment, proper work practices, and administrative controls.

## Reason for Policy/Purpose:

Work-related musculoskeletal disorders (MSDs) can result when there is a mismatch between the physical capacity of workers and their equipment and the physical demands of their job. According to the Occupational Safety & Health Administration (OSHA), each year 1.8 million workers in the United States report work-related MSDs such as carpal tunnel syndrome, tendonitis, and back injuries. About 600,000 MSDs each year are serious enough to prevent employees from working. Ergonomics can provide a solution to many of these injuries.

## Policy/Procedures

Proper application of ergonomic principles can help to reduce the risk of injuries or illnesses for employees working with computers, in laboratories, or in jobs involving repetitive motions and handling of heavy materials.

### Ergonomic Program promotes employee health and comfort through training, consultation, and written recommendations. The Laboratory Director is responsible for informing affected employees about work-related MSDs and associated risk factors, and encouraging employee involvement in promoting an ergonomically sound workplace.

### The primary tools of the laboratory’s Ergonomic Program includes training and information, symptom analysis, and workstation evaluations and recommendations. Employees may request an in-person ergonomic assessment of their workstation by filling out an ergonomic symptom survey, which is located on the server. Requests will be submitted to the Director of Operations on Quality Manual Attachment 16 Ergonomics Assessment checklist. Once a symptom survey is completed, an evaluation can be scheduled. No evaluations will be performed without the knowledge of the employee’s immediate supervisor. The Director of Operations will provide written recommendations to the employee, as well as his or her supervisor, which will outline possible alterations to the workstation. The purpose of the evaluation and written report are to eliminate ergonomic problems that may lead to musculoskeletal disorders, and to address MSDs already present. Only employees experiencing ergonomic difficulties should request an evaluation. The written report provided by the Director of Operations may include but are not limited to suggested products, such as keyboard trays or ergonomically designed chairs. Purchasing suggested products is both the decision and responsibility of the evaluated employee’s department.

# Reports of Device Related Incidents to the FDA

## Purpose:

To ensure that all employees are knowledgeable about reporting device-related adverse patient events as required by FDA.

### To keep effective drugs and devices available on the market for use, the FDA relies on the voluntary reporting of these events. FDA uses this data to maintain our safety surveillance of all FDA-regulated products. Your report may be the critical action that prompts a modification in use or design of the product, improves the safety profile of the drug or device and leads to increased patient safety

### The FDA Form 7500 (Quality Manual Attachment 17) should be used by healthcare professionals and consumers for voluntary reporting of adverse events noted spontaneously in the course of clinical care, not events that occur during IND clinical trials or other clinical studies. Those mandatory reports are to be submitted to FDA as specified in the investigational new drug/biologic regulations or investigational device exemptions. For instructions on mandatory reporting, go to <http://www.fda.gov/medwatch/getforms.htm>.

### **Procedure:**

Perform this procedure according to the following steps for the reporting of device-related adverse patient events, as required by FDA:

|  |  |
| --- | --- |
| Step | Action |
| 1 | Call the FDA at 1-800-FDA-1088 to report by telephone |
| 2 | Complete the Voluntary Reporting Form (3500) online by going to https://www.accessdata.fda.gov/scripts/medwatch/ or <http://www.fda.gov/medwatch/getforms.htm> and following the online instructions. |
| 3 | Download a copy of the form at <http://www.fda.gov/medwatch/getforms.htm> and then faxing the form to the FDA at 1-800-FDA-0178 or mail it back using the postage-paid addressed form. |

**Note:**

|  |  |
| --- | --- |
| Number | Notes |
| **1** | It is the responsibility of individual supervisors to ensure that all employees are knowledgeable of this process |

# BioSafety Level II Safety Manual

## Purpose

This manual provides a general overview of the facility and procedures for all personnel working in the BSL2 laboratory of the GENETWORx.

## Scope:

This SOP applies to all personnel that perform infectious disease testing for GENETWORx.

## Applicable Regulation and Guidelines:

Clinical Laboratory Improvement Amendment (CLIA) (CLIA 42 CFR Part 493)

## Responsibility:

All GENETWORx employees are responsible for adhering to all corporate procedures described. All personnel must receive training on all pertinent GENETWORx policies and procedures, and must adhere to all conditions as documented.

## Introduction

The BSL-2 facility involves moderate to agents and therefore requires a strict adherence to BSL-2 containment work practices and procedures. It is important that all personnel that work in the BSL-2 facility understand and adhere to the proper procedures and techniques outlined in this manual. Failure to adhere to appropriate practices and procedures may endanger others.

## Information about agents in use.

Unfixed human cells from blood, body fluid, or other tissues are used in the facility. All untested human samples should be considered potentially infectious for HIV, HBV and other bloodborne pathogens, which can infect humans through exposure of mucosal membranes to aerosol, broken skin or aerosol inhalation.

## BSL-2 personnel requirements

### All individuals working in the BSL-2 facility must be trained according to the compliance policies of the GENETWORx. Personnel receive annual updates, or additional training as necessary for procedural or policy changes. Additionally, the facility Director will conduct training for all personnel in the area, covering the potential hazards associated with the work, the necessary precautions to prevent exposures, exposure evaluation procedures, and the standard operating procedures of a BSL-2 laboratory. Facility Director is responsible for training employees concerning the hazards of the agents they will be working with and the proper laboratory techniques to use to avoid injury and illness. New employees must be trained prior to assignment in the lab. This training is to be documented in the employee's file with a listing of the session agenda, the name of the person providing the training, and the date and signature of the person trained. This record should be retained for the duration of employment and at least 3 years after.

### BSL-2 facility, layout, and air handling

#### BSL2 facility is located on the first floor of GENETWORx. Doors will be locked during sorting of unfixed, unknown human and non-human cells as well as after working hours and on weekend.

#### The airflow in the laboratory is regulated centrally by Facilities Management to maintain a specified number of air changes per hour. The room air pressure is negative with respect to the corridor. The LABCONCO hood is vented to the house air handling system.

### Medical requirements, hygiene, and good lab practices

#### All individuals present in the laboratory during the operation of BSL2 hoods must meet the following medical requirements:

#### All faculty and staff with exposure to human bloodborne pathogens are required to complete the following:

#### Those initiating work with materials potentially containing bloodborne pathogens are required to enroll in the GENETWORx Bloodborne Pathogen Exposure Control Program upon hire, and annual completion of BBP training.

#### Hepatitis B vaccination is strongly recommended and available without charge to individuals enrolled in the Bloodborne Pathogen Program.

### Basic hygiene

It is mandatory that all personnel wear personal protective equipment (lab coats and gloves) when handling human specimens or working on the instrument. When cleaning the inside of the Class II biosafety cabinet, a face protection shield or goggles should be worn. All personnel must wash their hands after removing gloves. Eating, drinking, storing food, handling contacts, and applying cosmetics are not permitted in the laboratory. Food must not be stored in refrigerators or freezers in the laboratory.

### General good laboratory practices

All unfixed specimens to be run on GENETWORx equipment should be handled in a Class II safety hood using universal precautions. Mandatory laboratory practices include use of mechanical pipetting, use of plastic instead of glass, minimizing the use of sharps (see Section 3.1.8 for Sharps policy), labeling equipment with appropriate biohazard stickers, and minimizing work with infectious substances on the open bench.

## Location, storage and use of BSL-2 agents

### **Purpose:** To provide a list of all agents used in the BSL-2 lab and their storage and use locations:

### Agents used in the BSL-2 lab

Unfixed or fixed human cells from blood, body fluid or other tissues. Generally, all the cells listed above are used immediately when they are brought to the lab. If the cells cannot be used immediately for some reason, they will be temporarily stored in the refrigerator.

## Procedures for the BSL-2 hood use

### Training requirements

All personnel must complete the following training prior to working in the BSL-2 laboratory. Training includes two Environmental Health and Safety training sessions (Bloodborne Pathogens and Chemical Hygiene training). Bloodborne Pathogen and Chemical Hygiene training are required on an annual basis.

### Workers cannot work in the BSL-2 lab unless all the training requirements have been met, they have read and signed off on the manual, and received approval from the Facility Director and Supervisor.

### Personal protective equipment.

Personal protective equipment (PPE) is designed to protect the worker from contact with biohazardous agents as well as to protect the work from contamination by the worker. PPE is considered a secondary line of defense against the infection. The primary line of defense is the use of Universal Precautions and good laboratory techniques. Mandatory PPE includes lab coats and gloves. When cleaning inside the hood, eyewear (safety goggles or face shield) must be worn.

### Biosafety cabinet (BSC).

#### There is 1 biosafety cabinet inside the BSL2 facility. It is a Class II biosafety cabinet in the DNA extraction lab.

#### **Signup sheet.** There is no mandatory sign up policy for the use of the Class II cabinet.

### Use of biosafety cabinets, and decontamination.

#### BSC’s are the most commonly used containment devices for preventing the escape of biohazardous materials into the laboratory environment. Four classes of BSC’s are recognized: Class I, Class II-Type A, Class II-Type B, and Class III. All four classes are suitable for work with biohazardous materials in BSL 1 to BSL 3. The Class III BSC is required for BSL 4 work. The sample manipulations (e.g. pipetting specimens into extraction tubes) prior analysis will be conducted inside the Class II biosafety cabinet. Prior to use, the blower and the lights of the BSC must be turned on. Make sure that the opening of the hood is at a safe operating level (10 inches). Minimize the working materials inside of the hood and make certain that they are placed well behind the ventilation unit in the front of the cabinet. Do not block the airflow. Keep contaminated materials separate from clean materials. After using the BSC, make sure to disinfect the hood as detailed in 3.1.4.2. When finished using the BSC, turn off the blower, close the door to the hood, and turn on the UV light.

#### Following use, spray the surfaces (horizontal and vertical) with Dispatch. Allow surface to air dry.

## Decontamination of biological waste.

### Liquid waste.

#### All liquid wastes generated during BSL-2 experiments should be immediately decontaminated by mixing with household bleach (6% sodium hypochlorite, final dilution not greater than 1:10) for at least 30 minutes contact time. The solution may then be disposed of in the sink; however, the sink must be washed and decontaminated after.

### Aspiration of liquid waste. No vacuum utility is available in the BSL2 facility.

### Solid waste.

#### Solid wastes generated during sorting unfixed unknown human tissue will be deposited into a biohazard bag located beaker within the hood. Waste and used gloves will be disposed in a biohazard bag in a labeled cardboard container. Full containers are sealed and removed by for autoclaving.

## Transportation of Agents.

Potentially infectious material transported into or out of the facility must be placed in a closed, leak-proof container labeled with a biohazard sticker.

## Centrifugation of Agents.

### There are two centrifuge in the BSL-2 laboratory. Prior to use, make sure that all samples are properly placed inside the centrifuge with balanced carriers and carrier safety caps. The centrifuge is to be decontaminated with Dispatch at the end of the day (on days that it is used).

## Sharps Policy in the BSL2.

The use of needles in the BSL2 laboratory should be minimized. Broken glass must be disposed of into a designated and labeled box for broken glass. If Sharps (needles, scalpels, etc.) must be used in the BSL-2 CDC Guidelines require the disposal of sharps in a designated harps box.

## Exit Procedures.

Before leaving the work area, all solid and liquid wastes are to be disposed of in the proper manner (see Section J). All equipment exposed to potentially biohazardous materials will be disinfected and returned to their correct place in the lab. Laboratory coats and gloves must be removed and disposed of in the biohazard solid waste container before leaving the lab.

## Equipment maintenance.

### Biosafety cabinets.

#### BSCs must be cleaned after each use. The surface of the BSC is wiped down with Dispatch solution. Keystone Services, Inc will certify BSCs once a year.

#### Centrifuges.

The centrifuge is to be cleaned and disinfected with Dispatch at the end of the day (on days that it is in use).

## Incubators

There are no incubators in the BSL2 facility.

## Spill response in the BSL-2 areas.

### Spills of biological materials are decontaminated, contained, and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious or potentially infectious material. Spills and accidents that result in overt exposures to BSL-2 materials are immediately reported to the Facility Directors. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are kept.

### Spills in Biosafety Cabinets Remove any contaminated clothing and change gloves. If needed, use the emergency shower and/or eyewash station located at the main lab of the facility. Cover with paper towels, surround the spill with disinfectant solution, and let mix for 20 minutes. Wipe down with a second application of disinfectant. Dispose all paper towels and PPE in a biohazardous waste bag. Leave the cabinet fans on.

### Spills outside Biosafety Cabinets Evacuate the area, close all the doors, and call the Facility Director or Supervisor.

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| Revision Number | Reason for Revision | Author | Effective Date |
| 1 | Change SOP number, reformat Quality System, Add CEO signature Line, move fire evacuation route and Fire Drill Form to separate files in Forms folder of the Quality manual | Sarah Jacobs-Helber | 07/21/17 |
| 2 | Add use of effective antimicrobial method for handwashing  | Sarah Jacobs-Helber | Upon Lab Director Signature |
| 3 | Addition of Laboratory Access Policy, UV Policy, Dry Ice policy | Sarah Jacobs-Helber | 08/21/2019 |

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| --- |
| **Review & Approval History** |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

**Reviewed by:**

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| **Printed Name** | **Signature** | **Date** |
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