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GUIDELINES FOR GOOD CLINICAL LABORATORY PRACTICE

Good clinical laboratory practice (GCLP) is an essential part of starting and maintaining a clinical laboratory. It is imperative for all of us who direct, manage, and work in clinical laboratories follow certain guidelines encompassing ethical and safety practices in addition to the level of efficiency we desire. GCLP contains standards derived from a combination of Clinical Laboratory Improvement Amendments (CLIA) (portions of 21 CFR part 58 (GLP) and 42 CFR part 493), accrediting bodies such as the College of American Pathologists (CAP) and the International Organization for Standardization (ISO) 15189, and other regulatory authorities and organizations. The British Association of Research Quality Assurance (BARQA) takes a similar approach by combining good clinical practice (GCP) and laboratory practices that are involved in laboratory research activities in Great Britain.

The GCLP standards developed by CLIA were done with the objective of providing a single, unified document that incorporates requirements to guide the conduct of laboratory testing for human clinical trials. However, they are also used in clinical laboratory testing of patients for the diagnosis, prognosis, and screening of human diseases. The intent of GCLP guidance is that when laboratories follow these processes, it ensures the quality and integrity of data, provides accurate reproducibility of experiments and testing, monitors data quality, and allows comparison of test results at any testing facility.

The information that follows synthesizes the GCLP standards based on the guidelines of CAP, CLIA, and ISO in order to facilitate implementation of GCLP for clinical laboratories. A comprehensive version of the GCLP standards with accompanying templates and examples is available at https://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf.

Cytogenetic Laboratory Management: Chromosomal, FISH and Microarray-Based Best Practices and Procedures, First Edition. Susan Mahler Zneimer.

Companion website: www.wiley.com/go/Zneimer/CytogeneticLabManagement

THE GCLP CORE STANDARD ELEMENTS FOR LABORATORIES TO ADHERE TO

1. Physical facilities
2. Specimen transport and management
3. Personnel safety
4. Laboratory information systems
5. Quality management
6. Organization and personnel
7. Laboratory equipment
8. Testing operating procedures

By recognizing these standards as the minimum requirements for optimal GCLP, compliance will result in consistent, reproducible, auditable, and reliable laboratory results for clinical testing.

In addition to these good laboratory practice (GLP) standards, other laboratory processes or plans need to be implemented, such as for the instruction of safety, biosafety, and chemical hygiene standards in the laboratory. Also, in the United States, patient health information is protected by law (Health Insurance Portability and Accountability Act (HIPAA)) and a plan must be developed in the laboratory for ensuring the security of patient information. These plans are necessary elements for GCLP and are required before clinical testing can be performed. The following standards for GCLP are outlined in this chapter:

- Safety Plan
- Biosafety Plan
- Chemical Hygiene Plan
- HIPAA Plan

These plans can be used by cytogenetic laboratories in order to comply with most regulatory agencies.

1.1 PHYSICAL FACILITIES

For GCLP, it is important to examine the facility you plan to use for your clinical laboratory in a myriad of ways. First, the environment in which laboratory testing is performed must allow efficient operations that do not compromise the safety of the staff or the quality of the preanalytical, analytical, and postanalytical processes. Developing new laboratory space or reconstructing current space needs to be carefully planned to account not just for efficiency and cost, but for the well-being of the staff and specimen processing. This would include implementing measures to avoid common errors seen in laboratories, such as ensuring enough walkway space, color-coding, and labeling areas for identification of processing, eliminating clutter, and adding storage space and personal space for the staff.

The laboratory design must account for equipment placement and proper ventilation. It must have a designated area for reagent storage and archiving of data in a secure fireproof, fire-resistant, or fire-protected environment with access only to authorized personnel, if possible.

Laboratory work areas must have sufficient space so there is no hindrance to the work or employee safety. Laboratory room (ambient) temperature and humidity must be controlled so that equipment and testing are maintained within the tolerance limits set by the manufacturer or laboratory. Ambient temperature logs should be used to document the acceptable ambient temperature range, record daily actual temperatures, and allow for documentation of corrective action should the acceptable temperature ranges be exceeded. All floors, walls, ceilings, and bench tops of the laboratory must be clean and well maintained.

Molecular amplification procedures within the laboratory that are not contained in closed systems must have a unidirectional workflow. This must include separate areas for specimen preparation, amplification, detection, and reagent preparation to avoid contamination and mix-ups between test and control specimens.

1.2 SPECIMEN TRANSPORT AND MANAGEMENT

The accuracy of all laboratory test results depends on the identity and integrity of the specimen submitted. We all know how difficult cytogenetic testing can be when an inappropriate or insufficient quantity of a sample is received for testing or if a sample gets lost in transit or is missing within the laboratory facility. Therefore, it is important to establish a sound specimen tracking system in the laboratory from collection to reporting test results in order to ensure the highest quality data and results. It is also important to ensure that clients sending samples to the laboratory know the laboratory specimen requirements.

The laboratory must also have documented procedures for collection, transportation, and receipt of specimens because the accuracy of all laboratory tests is dependent on specimen quality. A laboratory can only ensure specimen integrity when following appropriate specimen management and transportation procedures.

A properly completed requisition form must accompany each patient sample to the laboratory. The requisition form must contain unique patient identifiers, specimen collection date and time, patient demographics, and specimen type. Laboratory staff should verify that the specimen container with label information matches the requisition form and any log sheet that is present. Any discrepant or missing information must be verified promptly before specimens are processed or stored by the laboratory.

The laboratory must have documented specimen acceptance and rejection criteria for evaluation of sample adequacy and integrity. The laboratory must maintain an audit trail for every specimen from collection to disposal or storage. Audit trails must verify the date and time testing was performed and the personnel responsible for testing. All audit trails must be documented and accessible to auditors.

A shipping procedure must be documented that addresses preparing shipments by following all federal and local transportation of dangerous goods regulations (e.g., International Air Transport Association). Laboratory personnel handling specimens should be trained in hazardous materials/dangerous goods transportation safety regulations. Twenty-four hour monitoring of storage conditions, using manual and/or electronic monitoring with alert systems, and standard operating procedures (SOPs) for response to alerts must be in place to ensure that the integrity of samples is maintained.

1.3 PERSONNEL SAFETY

The safety of all laboratory staff is essential to avoid laboratory accidents and to prevent the acquisition of infectious agents through handling of specimens. Although exposure cannot always be avoided, every precaution must be taken to provide a safe working environment. Safety policies that are defined according to regulatory organizations, such as the Occupational Safety and Health Administration (OSHA) or the ISO, must be present in the laboratory.

THE FOLLOWING POLICIES MUST BE IN PLACE TO ENSURE THE SAFETY OF LABORATORY STAFF

- Standard universal precautions
- Chemical hygiene
- Hazard communication
- Waste management
- Safety equipment
- General safety and biosafety

These policies are described in more details later in this chapter. However, in general, fire extinguishers, emergency showers, eyewashes, and sharps containers must be present in each laboratory and in compliance with general safety and local laws. Periodic inspections and/or function checks of applicable safety equipment must be documented. The employer must provide the use of personal protective equipment (PPE) and provide access to PPE to all laboratory staff during clinical testing on human specimens. All laboratory employees must use PPE if there is a potential for exposure to blood or other potentially infectious material through any route (e.g., skin, eyes, other mucous membranes). The laboratory must have Safety Data Sheets (SDSs) or equivalent in the workplace for each hazardous chemical they use.

All laboratory staff must also receive safety training. See the Safety Plan further in the chapter for details.

AT A MINIMUM, SAFETY TRAINING MUST INCLUDE INSTRUCTION IN THE FOLLOWING AREAS

- Blood-borne pathogen handling
- Personal protective equipment (PPE) use
- Chemical hygiene/hazard communications
- Use of safety equipment in the laboratory
- Use of cryogenic chemicals (e.g., dry ice and liquid nitrogen)
- Transportation of potentially infectious material
- Waste management and biohazard containment
- General safety and related local laws

1.4 LABORATORY INFORMATION SYSTEM (LIS)

The laboratory information system (LIS) is an essential tool to manage complex processes and ensure regulatory compliance and good practice for clinical laboratories. The LIS should be capable of integrating various processes in the laboratory into a single platform with comprehensive specimen processing, reporting, surveillance, and networking capabilities.

The laboratory must maintain a written SOP for the operation of the LIS which should be appropriate and specific to the day-to-day activities of the laboratory staff as well as the daily operations of the information technology (IT) staff. Documentation must be maintained, indicating that all users of the computer system received adequate training both initially and after any system modification. Documented procedures and a disaster preparedness plan must exist for the preservation of data and equipment in the case of an unexpected destructive event (e.g., fire, flood, or earthquake), software failure, or hardware failure, allowing for restoring service as quickly as possible.

The purpose of the LIS, its functions, and its interaction with other devices or programs must be documented with validation data and results including data entry, data transmission, calculations, storage, and retrieval. Since patient management decisions are based on laboratory data, appropriate documentation in the LIS must exist to ensure data quality and integrity. Both abnormal and normal data must be used to test the system. Any changes or modifications to the system must be documented, and the laboratory director or designee must approve all changes before they are released for use. Computer time-stamped audit trails must be used by the LIS. The laboratory's LIS policies must ensure that LIS access is limited to only authorized individuals.

1.5 QUALITY MANAGEMENT

An overarching quality management (QM) program is essential to ensure the safety of patient samples and maintenance of quality laboratory operations. The QM program is a systematic approach to plan the achievement of quality objectives, comply with approved procedures, and assign specific functional responsibilities to laboratory staff. The QM program should also include a quality assurance (QA) program, which is set up to evaluate the laboratory's analytical performance by comparing test performances. The following information is an overview of the major components of a good QM program. More detailed information on QM is described in Chapter 2.

The laboratory QM program should be developed as an overall laboratory scope as well to monitor, assess, and correct specific problems identified in each of the preanalytic, analytic, and postanalytic steps in the laboratory testing process. As previously stated, a key component of the QM program is quality assurance (QA). QA must monitor for GCLP compliance, oversee the development of the QM program, and resolve quality-related problems as described earlier. The QA program should submit status reports to management and must prepare and respond to external audits. It must include evidence of appropriate follow-up actions taken as a result of monitoring in addition to evaluating the effectiveness of corrective actions.

The laboratory must provide evidence of implementation of the QM program (e.g., minutes of committee meetings, results of ongoing detection of errors, and documented complaint investigations). The laboratory must also be able to provide evidence of appraisal

of its QM program. That is, an annual written QM program with revisions including laboratory policies and procedures. QM program documentation must demonstrate at least annual review by the laboratory director or designee. The laboratory's QM program must include results of ongoing measurement of key quality indicators of laboratory operations compared to internal or external benchmarks and must be monitored for trends over time. The laboratory must be able to use the QM program for guidance when conducting annual appraisals of effectiveness and must provide evidence of the program's implementation.

THE QM PROGRAM SHOULD INCORPORATE THE FOLLOWING ELEMENTS

- Goals and objectives
- A design to monitor, evaluate, and correct quality problems
- The monitoring of complaints and incidents
- The monitoring of all aspects of the laboratory's scope of care
- Addressing problems that interfere with patient care
- Describing procedures for collection and communication of quality and safety information (e.g., QC and QA)
- Key quality indicators of laboratory operations that target quality improvements (QI measures), such as test turnaround time, specimen acceptability, and test result accuracy
- Evidence of a regular review by the laboratory director or designee

The laboratory's monitoring of the QM program must include an internal audit schedule that contains a comprehensive comparison of the actual practices within the laboratory to the laboratory's policies and procedures (e.g., personnel files, training documentation, quality control (QC) performance, review of SOPs). Internal audits involve an individual or a group of laboratory personnel performing periodic self-assessment of actual laboratory practices to see if it matches the laboratory's policies and procedures. All findings (compliance, noncompliance, or deficiencies) from an internal audit should be documented to allow for appropriate corrective action and follow-up through resolutions when appropriate. The laboratory should monitor that the QA Program covers all testing assays. The laboratory director or designee must document review of all external quality assurance data, and corrective action should be taken with appropriate preventive measures in response to any unacceptable results, which must be documented.

The laboratory must have a list of assay turnaround times readily available to all laboratory staff as well as laboratory customers. The laboratory must also have a nonretaliatory policy for employees to communicate concerns to laboratory management regarding testing quality or laboratory safety.

Within the QM program, all laboratories must include a QA program.

QA PROGRAMS SERVE THREE PURPOSES

- To provide an internal measurement tool for ensuring that the information a laboratory generates and provides is accurate, timely, clinically appropriate, and useful
- To provide regulatory agencies with confidence that individual laboratories are generating data with appropriate measures that will support licensure
- To ensure that specimens will be analyzed in a system that provides accurate and reliable results

Therefore, it is critical that laboratories provide a QA program that covers all testing protocols. The laboratory director or designee must review all QA data, and evidence of supervisory review of QA program results must be available (e.g., signature and date of reviewed results and documentation of corrective or preventive actions taken upon unacceptable results). QA specimens must be analyzed, quality assured, and reported in the same manner as patient specimens are tested in the laboratory. As an example, most of the clinical laboratory tests are covered by programs administered through CAP and other organizations.

Laboratories must also have a quality control (QC) program that defines procedures for monitoring analytic performance and consistent identification, documentation, and resolution of QC issues. This is important in detecting errors in a timely fashion as well as changes that occur over time in order to assure the accuracy and reliability of test results. In addition, the laboratory director and/or designee must determine the number and frequency of QC testing and the appropriate QC materials to use.

THE QUALITY CONTROL PROGRAM SUPPORTS FUNCTIONS IN THE FOLLOWING AREAS

- Test standards and controls
- Reagents
- Test specimens
- Review of quality control data
- Quality control logs, labeling of quality control materials and reagents
- Inventory control
- Parallel testing
- Water quality testing

More details of developing a QM program, audit preparation, and QA, QC, and QI programs are discussed in the Chapter 2.

1.6 ORGANIZATION AND PERSONNEL

Appropriately trained and well-organized laboratory staff are critical to the successful operation of a clinical laboratory. Laboratory systems are required to drive organizational structure, training, and ongoing competency assessment to ensure appropriate accountability for analyses of tests. The information that follows is an overview of the necessary laboratory requirements. Further detailed information regarding training and competency is discussed in Section II, Chapters 8–10.

A TESTING LABORATORY MUST HAVE THE FOLLOWING DOCUMENTS STORED IN THE LABORATORY

- Personnel policies that address such topics as orientation, training, continuing education, performance evaluations, benefits, discipline, dress codes, holidays, security, communication, attendance, and termination
- Job descriptions that define qualifications and delegation of duties for all laboratory positions
- Personnel files that document each employee's qualifications, training, continuing education, and competency assessments as they relate to job performance
- Organizational charts representing the formal reporting and communication relationships that exist among personnel and management and between the main laboratory unit and satellite units

All laboratory personnel must receive direct and detailed job-specific training and continuing education to perform all duties so they can understand and competently carry out the necessary SOPs. Competency assessment must be conducted at 6 months of the first year of employment and annually thereafter. Annual evaluations for the employee's overall performance of job responsibilities, duties, and tasks as outlined in the job description must be given to all laboratory personnel.

The laboratory must employ an adequate number of qualified personnel to perform all of the functions associated with the volume and complexity of tasks and testing performed within the laboratory. All laboratory staff signatures, initials, or codes used as staff identifiers on any laboratory documentation must be linked to a printed name list. This documented list should be a "controlled or traceable version" record that must be updated if changes occur in the laboratory. Signature logs should be archived so that those individuals who performed testing throughout the history of the laboratory are identifiable.

A clinical laboratory continuing education program that is adequate to meet the needs of all personnel must be documented, and evidence of ongoing adherence by all laboratory personnel must be readily available.

1.7 LABORATORY EQUIPMENT

Proper maintenance of all laboratory equipment is necessary for assays to function within manufacturers' specifications. Internal preventive maintenance activities as well as vendor-provided maintenance and repairs for laboratory equipment are essential in providing

accurate and reliable results. Laboratory staff must conduct preventive maintenance and service per manufacturers' specifications by following documented daily, weekly, and/or monthly routine maintenance plans for all equipment used to ensure that all equipment perform consistently and reproducibly during testing. The laboratory must also document all scheduled preventive maintenance, unscheduled maintenance, service records, and calibrations for all equipment utilized. This documentation should be readily accessible to the lab personnel. The laboratory director or designee must consistently review, sign, and date all documentation at least monthly to establish an audit trail.

The laboratory must also establish tolerance limits for equipment temperatures and other monitored conditions (e.g., % CO_2, liquid nitrogen levels) that are consistent with manufacturers' guidelines and procedural activities, since certain reagents and equipment perform optimally under specific conditions. The lab should also maintain daily records of temperatures and other monitored conditions (e.g., humidity). For observations that fall outside the designated tolerance ranges, the laboratory must maintain appropriate documentation of corrective action for these "out-of-range" temperatures and other conditions. More details on reagents, equipment, and instruments are described in Chapter 5.

1.8 TESTING OPERATING PROCEDURES

SOPs are critical for maintaining consistent test performance. The laboratory must write SOPs for all laboratory processes to ensure the consistency, quality, and integrity of test results. Current SOPs must be readily available in the work areas and accessible to testing personnel.

SOPs must be written in a manner and language that is understandable to the laboratory personnel conducting the procedures. SOPs should also be written in a standard format, such as the format recommended by the Clinical and Laboratory Standards Institute (CLSI), formerly the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). All laboratory personnel must document that they have reviewed and understood all relevant SOPs, so there is evidence that all personnel are knowledgeable in the tasks they perform as part of the laboratory SOPs.

THE LABORATORY MUST MAINTAIN A WRITTEN CURRENT DOCUMENT CONTROL PLAN THAT ADDRESSES AND ENSURES THE FOLLOWING VITAL ELEMENTS OF SOPs

- A master list of SOPs currently used in the laboratory
- An authorization process that is standard and consistent, limiting SOP approvals to laboratory management
- Assurance that all SOPs are procedurally accurate and relevant
- Review of each SOP at appropriate time intervals and when SOP content changes
- Removal of retired or obsolete SOPs from circulation and identification of them as retired or obsolete
- An archival system that allows for maintenance of retired or obsolete SOPs for a period defined by the laboratory that meets or exceeds the requirements of applicable regulatory bodies, such as the CLIA, FDA, CLIA, and ISO organizations

More details on operational SOPs are discussed in Section III.

The following sections include plans necessary for the ongoing operations of a cytogenetics (or any) laboratory. These plans include a safety plan, biosafety plan, chemical hygiene plan, and HIPAA incident plan. These plans can be downloaded as is or modified as needed by your own laboratory.

1.9 SAFETY PLAN

The purpose of this plan is to provide a comprehensive description of the environmental and safety requirements in a laboratory. The Safety Plan is an important part of GCLP and must be included in the laboratory's management processes. This plan includes:

- Injury and Illness Prevention Plan (IIPP)
- Hazard Communication (Haz Com) Plan
- Emergency Action Plan (EAP)

The Safety Plan references two additional hazard-specific safety programs, which are separate plans that are discussed later in this chapter: a Biosafety Plan and a Chemical Hygiene Plan. This plan covers all environmental and safety laws that apply to laboratories as well as general safety rules and policies to ensure safety compliance and to prevent occupational injuries and illnesses.

SAFETY PLAN POLICY

- Every employee is responsible for their own safety as well as others in the workplace. To achieve the goal of maintaining a safe workplace, everyone must be aware of safety issues at all times.
- To promote the concept of a safe workplace, an Injury and Illness Prevention Plan (IIPP), Safety Data Sheets (SDSs) of in-house hazardous chemicals, Hazard Communication (Haz Com), and Emergency Action Plan (EAP) all are part of this program.
- It is the policy that all personnel working on-site be trained on the Safety Plan. Additional training on chemical hazards and biohazards is provided as applicable to lab personnel.
- All workplace accidents and injuries shall be reported and investigated; OSHA-recordable injuries and illnesses shall be recorded on the annual OSHA Log 300 and Log 300A forms (Appendices 1.A and 1.B, respectively).
- There shall be regularly scheduled quarterly inspections (safety audits); deficiencies shall be corrected in a timely manner relative to the severity of the injury that could result.

1.9.1 Definitions

Commonly found definitions for the Safety Plan are described here.

DEFINITIONS

ANSI—American National Standards Institute.

OSHA—Occupational Safety and Health Administration.

Chemical safety—Safety requirements as they pertain to hazardous chemicals. A Chemical Hygiene Plan is required by OSHA's "Occupational Exposures to Hazardous Chemicals in Laboratories" Standard pursuant to Title 8 CCR §5191.

EAP—Emergency Action Plan. Procedures to follow in the event of a fire, evacuation, earthquake, etc.

EH&S—Environmental, Health, and Safety.

Hazard Communication Plan—The OSHA standard (Title 8 CCR §5194) that establishes minimum requirements for communicating hazards to workers. It requires SDSs for hazardous chemicals, explains proper container labeling, etc. It is also referred to as the "worker right-to-know" standard.

IIPP—Injury and Illness Prevention Plan, as required by OSHA Title 8 CCR §3203.

Log 300—Log of Work-Related Injuries and Illnesses. An OSHA form used to list annual workplace injuries and illnesses that are deemed "recordable." They must be written on the log within 7 days of identifying an incident.

Log 300A—Summary of Work-Related Injuries and Illnesses. An OSHA form used to summarize annual workplace injuries and illnesses that were reported on Log 300. It must be posted during the months of February and March for the preceding year.

SDS—Safety Data Sheet. A technical bulletin detailing information about on a hazardous chemical or a product with hazardous chemicals. Every chemical manufacturer or distributor must develop or obtain an SDS for each hazardous chemical it supplies, and every employer must keep them at the workplace.

Note: The United Nation's Globally Harmonized System of Classification and Labeling of Chemicals is now calling these SDSs instead of Material Safety Data Sheets (MSDSs); and OSHA has adopted this system in 2016.

1.9.2 Responsibilities

The laboratory safety officer and the quality assurance manager are jointly responsible for the following tasks, which may be handled by them directly, delegated to others, and/or done with the assistance of outside contractors or consultants.

TASKS TO BE IMPLEMENTED

- All safety officers and quality assurance managers are responsible for:
  - Handling all worker's compensation paperwork and maintaining OSHA Log 300
  - Referring personnel to the specified occupational health clinic as appropriate for injuries and medical surveillance
  - Providing guidance on safety matters

- Reviewing safety policies and programs at least annually
- Monitoring the procurement, use, and disposal of hazardous materials
- Ensuring maintenance of safety equipment such as fume hoods, safety showers, etc.
- Ensuring the collection and organizations of SDSs
- Ensuring all personnel receive appropriate safety training in a timely fashion
- Conducting accident investigations
- Conducting hazardous waste audits (when there is hazardous waste)
- Conducting safety audits and ensuring subsequent correction of noted deficiencies
- Ensuring that applicable environmental permits are obtained

- All managers and supervisors are responsible for:
  - Complying with safe and healthful work practices
  - Implementing and maintaining the safety of the employees in their work areas
  - Answering worker questions about the Safety Plan
- All workers are to:
  - Receive applicable safety training for their job assignments and be evaluated periodically on their safety performance and retrained as necessary if deficient
  - Report workplace accidents and injuries and fill out an Accident, Injury, and Incident Report Form

1.9.3 Communication

Employees are encouraged to ask questions and inform their managers and supervisors about specific issues regarding their work in the laboratory.

COMMUNICATION TOPICS

Communicate any workplace hazards without fear of reprisal.

- All managers and supervisors are responsible for responding to concerns and questions about occupational safety and health. This may be accomplished verbally one on one or by "on-the-bench" supervised training.
- Workers are encouraged to request workstation ergonomic evaluations for both the preventive and reactive modes (i.e., before symptoms appear and if they appear), with a focus on prevention.
- Workers are to exercise proper handling and lifting techniques of materials. They should know that when something is too heavy to lift alone, they should get help and/or use carts, hand trucks, or dollies when possible.
- Worker's compensation matters are usually addressed one on one between HR, the supervisor, and the affected employee.
- All managers and supervisors are responsible for responding to concerns and questions about occupational safety and heath. This may be done by email, memo, handouts/fact sheet, etc.

- Safety SOPs and plans and all referenced documents, references, and forms shall be kept current and readily available to staff.
- Affected employees will be notified of inspection findings, including noted deficiencies and planned corrective actions.
- Safety meetings may be utilized as an additional means to communicate safety information and to correct problems.
- Some safety information, such as evacuation routes and emergency contact numbers, shall be posted.
- New worker orientation shall include a discussion of safety and health policies and procedures, the "Basic Safety Training" course, and a determination of other EH&S Training that will be required.

1.9.4 Safety Training

All workers, including managers and supervisors, shall have training and instruction on general and job-specific safety and health practices. The "Group Training Record" will be used as the sign-in roster to document classroom training courses.

BASIC SAFETY TRAINING

- Includes IIPP, Haz Com, SDSs, safety equipment, use and locations, emergency procedures/response, and fire protection.
- Is required annually for every employee and regular on-site worker (including temp workers and consultants). All on-site personnel must participate in annual classroom training.

LABORATORY CHEMICAL SAFETY TRAINING

- Includes Haz Com, select carcinogens, hazardous waste handling, spill response, personal protective equipment (PPE), labeling, etc.
- Is required upon initial assignment to a laboratory or shipping/receiving area in addition to the occurrence of facility or operational changes (or compliance problems) necessitating a refresher course

BIOSAFETY AND BLOOD-BORNE PATHOGEN TRAINING

- Required annually for all laboratory and shipping/receiving workers.

FIRE EXTINGUISHER USE TRAINING

- Training on the use of portable fire extinguishers including both classroom and field training using real fire extinguishers and a real fire.
- For all workers who work in or enter the laboratory and/or shipping/receiving area of the facility. Topic is included in the Basic Safety Training, but hands-on training is to be provided by the laboratory at least every 2 years.

The applicable safety training is provided when the EH&S Program is first established. It also needs to be provided to all new workers and to all workers given a new job assignment for which training was not previously provided and whenever new substances, processes, procedures, or equipment are introduced to the workplace that represent a new hazard. In the event of a facility move or added building/build-out, the Basic Safety Training should be updated and provided anew.

In addition to classroom training, there must be at least one fire drill per year for on-site personnel, with or without the activation of alarms. Personnel must convene in the established outside emergency evacuation assembly area. This is included in the classroom version of the Basic Safety Training.

1.9.5 Accidents, Injuries, and Incidents

Different aspects of accidents, injuries, and incidents need to be recorded, including investigations, workers' compensation and OSHA recordkeeping and the procedure for reporting injuries.

INVESTIGATION OF ACCIDENTS, INJURIES, AND INCIDENTS

- Handle the medical emergency first, before the paperwork; always offer an injured worker the opportunity for medical care/evaluation.
- All workplace accidents, injuries, illnesses, or incidents will be investigated to determine if any preventable safety or health hazard contributed to the occurrence. The incident may or may not involve injury, illness, or a chemical exposure.
- The laboratory safety officer is responsible for conducting or overseeing the investigation within a timely manner after being advised of the incident. If a reportable serious injury or death results, he will ensure that a report is made to OSHA within 8 hours.
- The investigation details and findings shall be documented on the "Accident, Injury and Incident Report Form" even if there is no injury or illness.

WORKERS' COMPENSATION AND OSHA RECORDKEEPING

- For all cases involving an injury or illness beyond first aid, including those that result in loss of consciousness, or lost work time or reduced work activities on other than on the day of the injury, the laboratory must document the injury on a form that is provided by the laboratory's workers' compensation insurance provider. This must be done within 5 days of learning of the accident or illness.
- OSHA-recordable injuries and illnesses must be recorded on the current year's OSHA Form 300 "Work-Related Injuries and Illnesses Log" within 7 days of learning of it.
- Annually, OSHA Form 300 log entries must be summarized on an OSHA Form 300A (the "Summary of Work-Related Injuries and Illnesses") and must be posted for all employees to see.

INJURY REPORTING PROCEDURE

- Ensure the employee who has an injury has the ability to:
  - Be seen at an occupational health clinic
  - Obtain medical treatment beyond first aid, if needed
- Within 5 days of company knowledge of an injury, notify the workers' compensation carrier

1.9.6 Environmental and Safety Inspections/Audits

FREQUENCY OF INSPECTIONS

- Hazardous waste areas require weekly inspections in order to identify and correct potential hazardous problems.
- All facility locations should be inspected for safety at least quarterly.
- Periodic safety inspections should be conducted when new substances, processes, procedures, or equipment that present potential new hazards are introduced into the workplace.

HAZARD IDENTIFICATION

- Safety Data Sheets (SDSs) and other reference materials are used to identify the hazardous properties of hazardous chemicals kept on-site.
- Applicable OSHA standards and EPA regulations are used to determine proper safety requirements, including those concerning the handling, labeling, and storage of hazardous materials.
- The laboratory should also adhere to the standard associated with the potential for slips/trips/falls and ergonomic stress. Ergonomic evaluations and workstation modifications should be available upon request by an employee.
- If hazardous waste is present, the laboratory should adhere to the Laboratory Chemical Hygiene Plan, which should be covered in the Laboratory Chemical Safety Training course.

HAZARD CONTROL

- If the hazard discovered can cause a serious injury or illness ("an imminent hazard"), it shall be corrected immediately, or employees shall be removed from the area, source of exposure, or unsafe piece of equipment.
- If the hazard is one that is easily abated, it shall be corrected immediately.
- Documentation used in discovering the hazard will be used to confirm abatement (e.g., noting the correction on an inspection checklist or an injury and illness investigation form).

1.9.7 Emergency Action Plan (EAP)

BUILDING EVACUATION

- Evacuation maps shall be posted throughout the facility in main points of traffic flow to assist personnel in locating the nearest exit doors.
- The evacuation maps shall indicate the location of the assembly area.
- Personnel shall be trained on the evacuation procedure at least annually by means of a drill.
- Personnel need to know how to activate the alarm system, if necessary.

EMERGENCY COORDINATORS

- Identify key personnel who will serve as emergency coordinators who are responsible for checking names in the assembly area after a building evacuation.
- Ensure the current emergency coordinators are listed on the most current emergency contact list.
- Emergency coordinators are to receive separate training regarding their responsibilities, the contents of the emergency supplies backpacks, and the use of a megaphone and radio.

EMERGENCY CONTACT LIST

- A current emergency contact list shall be posted and given to each employee when it is issued or revised.
- The emergency contact list shall include agency and company contacts, information of the assigned occupational health clinic and nearest hospitals, etc.

INJURIES AND ILLNESSES

- Ensure there are provisions for medical services and first aid at a local clinic.
- Ensure there are at least two first aid kits available on-site: one in a breakroom and one in the corridor outside the labs.
- Ensure personnel know when to contact 911 services and to stand outside to flag down emergency vehicles.
- Ensure workers know that all workplace injuries and illnesses must be reported.

FIRE PREVENTION AND CONTROL

- Do not store materials, boxes, or other items within 18 inches of the ceiling.
- Minimize the amount of flammable and combustible liquids kept on-site.
- Store flammable and combustible liquids in approved flammable storage cabinets.
- Ensure there is no smoking in the building.
- Keep ignition sources away from flammable and combustible materials.

- Minimize the amount of "in-use" flammable liquids, and keep them covered when not in use, and/or capture the vapors with a fume hood or other local exhaust ventilation system.
- Minimize the use of metal tools near or with flammable liquids. Only use nonsparking tools in areas where flammable liquids are stored or used.
- Do not store items within 36 inches of electrical panels.
- Minimize the potential for creating static electricity sparks when transferring flammable liquid from one container to another, that is, ensure container-to-container contact and pour slowly.
- Employ proper grounding of any containers of flammable liquids that are 5 gallon or greater in size.
- Keep incompatible chemicals separate from each other.
- Do not accumulate flammable or combustible material. Throw out extra boxes and other combustible materials. Take trash out daily and place boxes in recycling containers daily.

ALARM SYSTEM

- The facility is equipped with a central alarm system to notify occupants. Manual pull stations and smoke detectors are located throughout the building. The fire detection system is inspected and tested annually. Records of inspections and tests are maintained by the building owner.

SPRINKLER SYSTEM

- The facility is equipped with a fire suppression sprinkler system. The sprinkler system is inspected quarterly and the main water riser is inspected every 5 years. Records of inspections are maintained by the building owner.

FIRE EXTINGUISHERS

- The building is equipped with portable ABC-type fire extinguishers. ABC extinguishers are acceptable for use with materials such as wood, paper, cloth, chemicals, and electrical equipment.
- The locations of the fire extinguishers are clearly marked and are also indicated on the posted Evacuation and Safety Equipment Map.
- Portable extinguishers are to be maintained in a fully charged and operable condition or else removed.
- Extinguishers will be pressure-tested and certified by a qualified company at least annually.
- Training for fire extinguisher use:
  - Fire extinguisher use training will be offered at least every 2 years. The training shall include both classroom and field training using real fire extinguishers and a real fire. All employees are urged to attend.

EXPLOSIONS AND MODERATE TO LARGE EARTHQUAKES

- Seek cover under a table, desk, or near a structural support until the shaking, rumbling, and/or blasts stop.
- Assess the situation to identify injured personnel and a safe path of egress. If possible, help injured personnel vacate the building.
- Evacuate the building and attend to injured personnel, if possible.
- Activate the alarm or call 911, as needed.
- Wait at the assembly area until your name is checked off.
- Do not reenter the building until you are told it is safe to do so.

POWER OUTAGES

- Plan ahead by identifying equipment that needs emergency power and/or a uniform power supply.
- Ensure backup generators are working.
- Label outlets that are on emergency power.
- Supplement the building's emergency lighting with an adequate supply of plug-in power failure lights. Place them in rest rooms, storage rooms, and areas inadequately lit with the standard emergency lighting.
- Maintain a battery-powered radio.
- Plan ahead with IT and operations personnel to identify which equipment to manually unplug before the power comes back on.

1.9.8 General Workplace EH&S Practices

Maintain the workplace and safety equipment (e.g., eyewash, fume hood, spill kits, etc.) as specified by OSHA or ANSI: annually for fire extinguishers and fume hoods and weekly for emergency showers and eyewashes.

BEST PRACTICES FOR WORKPLACE SAFETY

- Ensure tall cabinets and unstable equipment are seismically braced.
- Ensure shelves with heavy objects and hazardous chemicals have seismic lips.
- Maintain proper housekeeping to keep stairways and aisles clear and work areas neat and orderly.
- Ensure proper storage to prevent stacking of goods in an unstable manner and/or storing goods against doors, exits, fire extinguishing equipment, and electrical panels.
- Label all chemical containers, and place liquid waste containers in secondary containment.
- Place start dates on all chemical waste collection containers when an item is declared waste or when the first drop of waste is collected. Use the designated hazardous waste labels.
- Post hazard information on the entrance to lab areas and on exterior building doors in accordance with the local Fire Department.

- *Do not* eat, drink, or store food and drink in lab areas.
- *Do not* wear lab coats outside of lab areas.
- All personnel shall wear the correct personal protective equipment (PPE) for the assigned job when entering the laboratory and remove it when exiting the laboratory. Personal protective equipment shall include:
  - Laboratory coats or gowns
  - Gloves
  - Goggles or other approved protective eyewear
- A voltmeter will be used to verify the grounding safety of all new lab equipment at the time of installation and whenever equipment is relocated to a new location.
- Ultraviolet (UV) light safety is practiced for equipment having UV lamps.
- All equipment with ultraviolet light lamps, which include the biosafety cabinets and PCR stations, must be posted with warning signage that indicates the hazards to the eyes and skin.
- Personnel shall be instructed to turn off the lamps while working at/in the equipment having UV lights.
- The need for additional shielding may be warranted, as determined by EH&S.
- Personnel shall be instructed to keep the glass sashes on the biosafety cabinets closed when the UV lights are turned on.
- An UV lamp meter will be available on-site to measure lamp intensity at least every 6 months and when lamps are replaced.
- These rules shall be discussed in the annual Biosafety/Bloodborne Pathogen Training.

1.9.9 Recordkeeping

EH&S RECORDS SHALL BE KEPT ON FILE FOR THE PERIOD INDICATED BELOW

- Written EH&S Programs and Associated Document—Indefinitely
- OSHA Log 300 and 300A Forms—5 years following the end of the calendar year the records cover
- Inspection/Audit Forms—3 Years
- Accident/Incident Investigation Forms—5 Years
- Employee Training Forms:
  - Personnel Records—Duration of employment
  - Training Sign-Up Sheets—Minimum of 3 years
- Records Relating to Employee Communication and Enforcement:
  - Safety Meeting Sign-Up Sheets—3 Years
  - Disciplinary Actions—3 Years
- All Other Safety Records—3 Years
- Medical and Employee Exposure Records—Duration of Employment +30 Years

1.10 BIOSAFETY PLAN

The Biosafety Plan has been prepared to minimize or eliminate employee exposure to blood-borne pathogens. It was developed in accordance with the OSHA "Occupational Exposure to Bloodborne Pathogens: Final Rule" contained in 29 CFR Part 1910.1030 (December 1991), which was subsequently revised in January 2001 (effective April 18, 2001) under the title: "Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries, Final Rule" (the "Standard").

Blood-borne pathogens are pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). In addition to human blood and blood products, the following fluids and tissues, called "other potentially infectious materials (OPIM)," are also capable of transmitting blood-borne pathogens.

OTHER POTENTIALLY INFECTIOUS MATERIALS

- Semen and vaginal secretions
- Cerebrospinal, synovial, pleural, pericardial, peritoneal, and amniotic fluid
- Saliva in dental procedures
- Any body fluid that is visibly contaminated with blood
- All body fluids in instances where it is difficult or impossible to differentiate between body fluids
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead)

HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV/HCV-containing culture medium or other solutions are also subject to the OSHA Bloodborne Pathogens Standard.

1.10.1 Policy

The policy of the Biosafety Plan is that all human blood, blood products, or OPIM must be handled with universal precautions, that is, as if all such materials were infected with blood-borne pathogens.

DEFINITIONS

Blood-borne pathogens (BBP)—Pathogenic microorganisms that are present in human blood (blood-borne pathogens) which can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

ECP—exposure control plan.

Exposure Incident—A specific eye, mouth, other mucous membrane, nonintact skin, or parenteral (e.g., needlesticks, human bites, cuts, and abrasions) direct contact with blood or other potentially infectious materials (OPIM).

NIOSH—National Institute for Occupational Safety and Health.

Occupational exposure—Reasonably anticipated skin, eye, parenteral contact, or mucous membrane contact with blood or other potentially infectious material (OPIM) that may result from the performance of an employee's duties.

1.10.2 Exposure Determination

The standard requires that each organization assess whether or not its employees are subject to occupational exposure to blood-associated pathogenic microorganisms. Exposure determinations are made by reviewing all job classifications and placing them into work exposure groups. The first exposure group includes job classifications in which all of the employees have occupational exposure, such as occupational health nurses, phlebotomists, researchers who work with human blood and blood cells, emergency response personnel, etc. The second exposure group includes those classifications in which some of the employees have occupational exposure. An example would be in a laboratory where some of the workers might be assigned the task of handling blood or OPIM while other workers wouldn't.

Occupational exposure is defined as a reasonably anticipated skin, eye, mucous membrane, or parenteral contact (i.e., needlestick) with blood or OPIM that may result from the performance of an employee's duties.

JOB CLASSIFICATIONS: SPECIFIC TASKS AND PROCEDURES

Group 1—Occupational exposure as part of the job:

- Laboratory scientists and other lab staff who work with fresh or frozen (unfixed) human fluids and tissues

Group 2—Staff that may have occupational exposure:

- Receiving personnel who first handle and accession incoming specimens of fresh or frozen (unfixed) human fluids and tissues
- Personnel who work in a lab where Group 1 work (even if they themselves do not handle said specimens), but who use the same equipment, such as fume hoods, work benches, centrifuges, etc.

1.10.3 Responsibilities

Supervisors are to ensure compliance with the provisions of this plan for all employees who have a potential for occupational exposure. This includes providing a copy of this exposure control plan to employees, enforcing compliance with this plan, ensuring new employees are properly trained, ensuring all employees attend an annual training session, and performing follow-up procedures for all exposure incidents.

Employees are to perform tasks and procedures in a manner that minimizes or eliminates employee exposure and perform duties as established in this exposure control plan and as trained. Employees are to report exposure incidents.

Facilities/EH&S provide or arrange the OSHA-mandated blood-borne pathogen information and training sessions at least annually to each employee with occupational exposure. EH&S provides assistance with the medical surveillance and recordkeeping. Facilities/EH&S also ensure that this plan is reviewed and updated at least annually.

1.10.4 Methods of Compliance

Work with blood-borne pathogens is considered "Biosafety Level 2" work by the Centers for Disease Control (CDC). There are four biosafety levels in all, with Level 1 being the one used for the lowest-risk biological work and Level 4 being the one used for the highest-risk biological work. The CDC publishes a book jointly with the National Institutes of Health (NIH) called "Biosafety in Microbiological and Biomedical Laboratories" (see http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf) which describes all of the biosafety levels and the appropriate methods of compliance. A further description of biosafety levels is seen in Chapter 2.

The following describes both general and specific procedures based on Biosafety Level 2 criteria:

Universal precautions "Universal precautions" is the practice of assuming that anything could be potentially infectious is infectious; therefore, all such samples or fluids are treated with the same regard. Universal precautions are observed to prevent contact with blood or OPIM, such as the human primary cell lines. Under circumstances in which differentiation between infected and noninfected body fluid types is difficult or impossible, such as emergency response situations, all body fluids are considered potentially infectious materials.

Engineering controls Engineering controls are to be used to eliminate or minimize employee exposure for each task within the work area. Where occupational exposure remains after institution of these controls and work practice controls, PPE is used. Engineering controls, when possible to implement, are the preferred control measures over work practice controls and PPE.

OSHA has specific requirements as it pertains to the use of needles in activities with human blood, tissues, and OPIM. When using needles with these materials, the use of safety needles is required unless at least one of the four following exemptions applies.

USE OF SAFETY NEEDLES IS NOT REQUIRED UNDER THESE CIRCUMSTANCES

- Employer shows that no needleless systems or sharps devices with engineered sharps injury protection are available in the marketplace for their procedure.
- A licensed healthcare professional directly involved with a patient's care determines that available needleless systems or sharps devices with engineered sharps injury protection would compromise the patient's care or safety.

- Employer shows that available needleless systems and sharps devices with engineered sharps injury protection are not more effective in preventing exposure to blood-borne pathogens than the alternative they are using.
- Employer shows that sufficient information is not available on the safety performance of the needleless systems and sharps devices with engineered sharps injury protection available in the marketplace, and the employer is actively evaluating such devices.

When a sharps container reaches a capacity of 2/3 or more (but not more than full), the person responsible for that container is to seal it and dispose of it as medical waste if contaminated (or as nonregulated sharps, if not contaminated).

All medical waste containers, if any, are surveyed at least weekly to ensure there are no leaks. When full, and at least once per week, the red biohazard bag within each medical waste container is sealed shut (via a knot, tape, rubber band, etc.) and transported within a secondary containment to medical waste collection barrels.

1.10.5 Work Practice Controls

MINIMUM WORK PRACTICE REQUIREMENTS

- Hands are washed immediately or as soon as feasible after removal of gloves or other personal protective equipment.
- Following contact with unfixed human fluids and tissues, hands and any other skin will be washed with soap and water. Mucous membranes (mouth, nose, and eyes) are flushed with water.
  - **Equipment locations:** Sinks with handwashing supplies are located in or near every lab. A combination safety shower/emergency eyewash is located in or near every lab area.
  - **Equipment testing:** The eyewashes and showers are inspected and tested at least monthly, and these are recorded.

In addition, the following regulations should be adhered to the following:

- Contaminated needles and other contaminated sharps are not to be bent, sheared, or broken.
- Recapping needles by hand is prohibited. Recapping and needle removal must be accomplished through the use of a mechanical device.
- Immediately or as soon as possible after use, contaminated sharps must be placed in puncture-resistant, labeled, leakproof sharps containers. The sharps container must be near the point of use.

- Eating (chewing gum, use of throat lozenges), drinking, smoking, applying facial cosmetics (including lip balm), and handling contact lenses are prohibited in all work areas. Prior to the consumption of any food after handling potentially infectious materials, employees will remove potentially contaminated PPE, wash hands, and exit the work area.
- Food and drink are prohibited in lab or work areas (i.e., refrigerators, freezers, shelves, cabinets, and on countertops or bench tops where blood or OPIM are present).
- All procedures involving unfixed human tissues and fluids are performed in a manner that minimizes splashing, spraying, spattering, and generation of droplets of these substances:
  - Centrifuging: When samples are centrifuged, they are centrifuged with the caps/lids on.
  - Goggles for eye protection are required.
- Mouth pipetting/suctioning is prohibited.
- Specimens of potentially infectious materials taken outside the building are labeled and placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. The container is closed prior to storing, transporting, or shipping.
- If outside contamination of the primary container occurs (e.g., a test tube), the primary container is placed within a secondary container that prevents leakage during handling, processing, storage, transport, or shipping.
- Secondary containers are used whenever potentially infectious materials are transported from one laboratory to another. Samples may be placed into plastic bags, transported in a tray or pan, or carried in a bucket or pail. The primary container should not extend over the height of the secondary container (e.g., a flask of cell culture should be transported in a pail or some such deep carrier—and not a shallow tray.)
- Equipment which may become contaminated with potentially infectious materials is examined by the employee prior to servicing or shipping and will be decontaminated as necessary, unless demonstrated that decontamination of the equipment or portions of such equipment is not feasible. A readily observable label with the universal biohazard symbol is attached to the equipment stating which portions remain contaminated.

1.10.6 Personal Protective Equipment (PPE)

Selection of PPE to use:

- PPE shall be provided by the company (or laboratory) at no cost to the employees.
- Appropriate PPE may consist of, but is not limited to, gloves, gowns, lab coats, face shields, masks, eye protection, mouthpieces, resuscitation bags, pocket masks, and other ventilation devices. PPE is considered appropriate if it does not permit blood or OPIM to penetrate the employee's work clothes, street clothes or undergarments, skin, eyes, or other mucous membranes under normal working conditions and for the duration of time that PPE shall be used. It is the employee's responsibility, when there is occupational exposure, to use the appropriate PPE.
- Face shields or safety glasses are worn whenever there is a risk of splashes to the face or eyes or when large volumes of potentially hazardous fluids are handled.

- Masks in combination with eye protection devices, such as goggles or glasses with solid side shields or chin-length face shields, are worn whenever splashes, spray, spatter or droplets of blood, or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- Latex or nitrile gloves are worn whenever potentially infectious materials are handled or when it can reasonably be anticipated that the employee may handle potentially infectious materials. Hypoallergenic gloves, glove liners, and similar alternatives will be made available to employees who have a documented allergy to the gloves that are usually supplied to their work area.

How to handle the used PPE:

- When leaving the laboratory, workers remove their gloves and wash their hands with soap and water. Lab coats are hung on the coat rack, and goggles are placed in the appropriate location.
- Disposable personal protective garments, gloves, face masks, etc. that are contaminated are to be removed immediately, or as soon as feasible, and prior to leaving the work area. When removed, they are immediately placed into a medical waste container lined with a red bag.
- Disposable gloves are replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
- Disposable gloves are not washed or decontaminated for reuse. Utility gloves (i.e., rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures can be used. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, discolored or if they have puncture, tears, or other evidence of deterioration or their ability to function as a barrier is compromised.
- Contaminated reusable (cloth) lab coats and garments, when visibly and/or known to be contaminated with potentially infectious materials, are to be bagged and placed in the appropriately designated container. These bags of contaminated laundry are to be labeled with the universal biohazard symbol unless personnel choose to disinfect their contaminated coats themselves, prior to sending them out. Employees are not allowed to take contaminated clothing home to launder.
- Employees who have contact with contaminated laundry will wear gloves and other appropriate PPE. After removal of the gloves, hands are then washed with soap and water.

1.10.7 Housekeeping, Decontamination, and Spill Response

- The work site is maintained in a clean and sanitary condition according to a schedule for cleaning and methods of decontamination.
- Lab benches not lined with bench liners are cleaned with a solution of 70% ethanol, 70% isopropanol, or 1% household bleach by the lab staff upon completion of their work at the end of the day. Floors are washed regularly.
- All equipment and working surfaces are to be cleaned and decontaminated after contact with blood or OPIM. Contaminated work surfaces are to be decontaminated

with an appropriate disinfectant after completion of procedures, immediately or as soon as feasible when surfaces are overtly contaminated, or after any spill of blood or OPIM and at the end of the workday.

- Protective coverings (plastic wrap, aluminum foil, bench liner, etc.) used to cover equipment and surfaces shall be removed and replaced as soon as feasible when they become contaminated and on a regular basis. NOTE: Bench liner is a common source of contamination and cannot be disinfected like a countertop.
- Broken glassware will not be picked up directly with the hands. Mechanical means, such as tongs, forceps, or a dustpan, will be utilized. A dustpan and brush should be located in or near every laboratory area. All of these tools must be disinfected after use, before returning them to their designated storage locations.
- Spill response procedures and liquid waste decontamination procedures are essentially the same. Wear PPE (gloves, goggles, etc.) and treat with a 1:10 dilution of household bleach (i.e., a 10% solution) and allow to stand for at least 10–15 minutes prior to cleanup or disposal. In the event that the area around a broken glass cleanup is contaminated, then the area is to be flooded with the bleach solution prior to cleanup.
- Contaminated sharps devices are discarded immediately or as soon as feasible in covered, puncture-resistant, leakproof, labeled containers. Containers will not be allowed to overfill. Containers are replaced when they are 2/3 or more full.
- Regulated waste ("medical" waste and sharps) is to be placed in covered leakproof, labeled containers that are closed prior to removal. If outside contamination of the container occurs, it is placed in a second container that is also leakproof, labeled, and closed prior to removal, or it may be disinfected with a disinfectant.

1.10.8 Labels and Signs

There are labeling requirements for specimens and samples and the equipment (centrifuges, refrigerators, and freezers, etc.) used to store and process the samples, medical waste, and contaminated laundry. In addition, all doors leading to Biosafety Level 2 areas should be posted as such and have emergency contact information. All must bear the universal biohazard symbol.

1.10.9 Medical Surveillance

The laboratory should make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure and postexposure evaluation and follow-up to all employees who have had an exposure incident. All medical evaluations and procedures including the hepatitis B vaccine and vaccination series and postexposure evaluation and follow-up, including prophylaxis, are made available at no cost to the employee.

Hepatitis B Vaccination

- Hepatitis B vaccination is made available to the employee after his/her attendance at a blood-borne pathogen training and information session. All potentially exposed personnel must read information regarding HBV and the HBV vaccination. The information should allow personnel to indicate their HBV immune status and select

vaccination options. The vaccine is made available to all employees with occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, the vaccine is contraindicated for medical reasons, or the individual declines. The vaccine will be provided according to current recommendations of the US Public Health Service.

There is no current recommendation for booster doses. However, CDC recommends routine postvaccination serologic testing for healthcare workers with ongoing risk of sharps-related exposure incidents. (See "Centers for Disease Control and Prevention. Immunization of Health Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recommendations and Reports. December 26, 1997. Volume 46, Number RR-18" (see http://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm).) Postvaccination testing should be conducted as detailed in the latest recommendations of the CDC.

All potentially exposed employees who decline to accept the hepatitis B vaccinations will be required to sign a Hepatitis B Vaccine Declination Form in accordance with OSHA requirements. If an employee decides to accept the vaccination at a later date, the vaccination series will be made available at that time.

1.10.10 Postexposure Evaluation and Follow-Up

An exposure incident is defined as a specific eye, mouth, other mucous membrane, noninact skin, or parenteral (through the skin) contact with blood or "OPIM" that results from the performance of an employee's duties. If an exposure incident occurs, the following steps must be taken without delay:

- Wash the exposed area immediately with soap and water. If there is a cut, wash the area with soap and water and allow the area to bleed freely. If blood or other potentially infectious body fluids enter the eye, nose, or mouth, flush with water for at least 15 minutes.
- Report the incident to your supervisor immediately. He/she will begin completing the necessary reporting forms and will ask for your assistance so that the facts of the incident can be documented. If an object, for example, needle, broken glass, etc., is part of the incident, save the object by placing it in a plastic bag or other container.
- Report immediately to the designated occupational health clinic or for additional support and medical attention.

For all exposure incidents, the route(s) of exposure and the circumstances under which the exposure incident occurred are documented. The source individual is identified and documented, unless identification is not feasible or prohibited by state or local law. After consent is obtained, the source individual's blood is tested for HBV and HIV status. If the exposed employee gives consent, a baseline blood sample is collected immediately following the incident with subsequent periodic samples taken at a later date.

Results of the source of the individual's testing will be made available to the exposed employee, and the employee will be informed of laws and regulations regarding the privacy rights of the source individual. The results of the source of the individual's blood test and employee's blood test are confidential and will be known only to the exposure nurse or physician and the exposed employee. Counseling and other features of postexposure evaluation will be offered whether or not the employee elects to have baseline HIV/HBV serological testing.

The latest information on postexposure prophylaxis may be found at "A Quick Guide to Postexposure Prophylaxis in the Healthcare Setting," which is available at http://www.mpaetc.org/MPAETC/media/MPAETC/Product%20Downloads/pep_steps.pdf. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-Exposure Prophylaxis.

OSHA requires that employers maintain a needlestick injury log of all incidents involving human blood and other defined potentially infectious materials.

1.10.11 Hazard Communication and Training

Supervisors are to ensure that employees with occupational exposure to blood-borne pathogens participate in a training program. Employees are to complete training at the time of initial assignment to tasks where occupational exposure may take place and at least annually thereafter.

An instructor should be available to deliver the initial course, but refresher training may make use of other means including videotapes, written materials, and computer-assisted training. Additional training requirements apply to employees in HIV and HBV laboratories and production facilities. The supervisor ensures that employees demonstrate proficiency in standard microbiological practices and operations specific to the facility before being allowed to work with HIV or HBV and have prior experience in the handling of human pathogens or tissue culture. The supervisor ensures that employees who participate in work activities involving infectious agents will do so only after proficiency has been demonstrated.

1.10.12 Recordkeeping

TRAINING RECORDS

- Training records are kept at least 3 years from the date on which the training occurred.
- All training sessions are documented in writing, with records kept by EH&S. The training record includes:
  - Dates of training sessions
  - Contents of training sessions
  - Names/qualifications of persons conducting training
  - Names/job titles of all persons attending training sessions

MEDICAL RECORDS

- Confidential medical records for employees with occupational exposure are kept for the duration of employment plus 30 years. Medical records shall include:
  - Employee's name and Social Security number
  - Employee's hepatitis B vaccination status including vaccination dates and any medical records related to the employee's ability to receive vaccinations
  - Results of examinations, medical testing, postexposure evaluation, and follow-up procedures
  - Healthcare professional's written opinion
  - A copy of the information provided to the healthcare professional

The occupational health clinic ensures that employee medical records are kept confidential and are not disclosed or reported without the employee's written consent to any person within or outside the workplace except as required by this protocol and by law.

1.11 CHEMICAL HYGIENE PLAN

The laboratory should be committed to the health and safety of its employees working in laboratories. To assure implementation of this commitment, a Chemical Hygiene Plan has been developed to advise employees of the hazards associated with laboratory chemicals and to keep exposures to these chemicals at a minimum through engineering controls (ventilated hoods and cabinets), administrative controls (safe work practices), and PPE.

Lab employees receive training on the elements of the program, including chemical hazards and personal responsibilities. Any person with an assigned responsibility under the Chemical Hygiene Plan who knowingly fails to comply with the plan may be subject to appropriate disciplinary action. This plan complies with requirements of the "OSHA" set forth in 8 CCR §5191 of the General Industry Safety Orders, "Occupational Exposures to Hazardous Chemicals in Laboratories."

1.11.1 Roles and Responsibilities

1.11.1.1 Chemical Hygiene Officer The chemical hygiene officer is responsible for ensuring that the Chemical Hygiene Plan is effectively implemented and performs the following duties:

- Works with facility personnel to develop appropriate chemical hygiene policies and practices, including the regular maintenance of engineering controls such as emergency showers, eyewashes, and fume hoods
- Monitors the procurement, use, and disposal of chemicals used in the lab
- Oversees the collection and organization of the SDSs
- Assists in conducting audits, correcting deficiencies, and maintaining appropriate documentation

- Helps laboratory personnel evaluate hazards and devise adequate protective practices and facilities
- Seeks ways to improve the chemical hygiene program, including at least an annual review of the written program
- Ensures training for laboratory employees
- Advises laboratory supervisors and management of any chemical hygiene problems in the laboratory and employee concerns

1.11.1.2 Senior Management Senior management has overall responsibility for occupational safety and health at the facility, including laboratory chemical hygiene. Senior management directs all laboratory management and supervisory personnel and employees to implement this chemical hygiene program and comply with all applicable requirements.

The Chemical Hygiene Plan seeks to minimize chemical exposures to the extent feasible by a combination of:

- Employee training on hazard recognition and safe work practices
- Making available the necessary ventilation control equipment, safety equipment, and PPE
- Maintaining housekeeping and work area orderliness
- Routine inspections
- Enforcement of line management responsibilities

1.11.1.3 Laboratory Managers/Directors Laboratory managers or directors have day-to-day responsibility for assuring implementation of the Chemical Hygiene Plan by employees in the laboratory. Laboratory manager/directors are responsible for the following:

- Knowing the basic elements of the Chemical Hygiene Plan, including the chemicals of concern (i.e., those that are highly toxic, chronic toxins, carcinogenic, etc.)
- Ensuring that workers know and abide by chemical hygiene rules, use protective equipment, and receive adequate training
- Assisting in determining the required levels of protective equipment and apparel
- Ensure the availability and performance of engineering controls (e.g., fume hoods, dust control)
- Responding effectively to employee questions, requests for information, and concerns about chemical hygiene

1.11.1.4 Laboratory Employees The following requirements apply to every laboratory employee:

- Comply with all general and specific safety rules and safe work practices applicable to any work task or procedure, including but not limited to those in this Chemical Hygiene Plan.
- Know the hazards and properties of all chemicals used.

- Know what to do in an emergency, including but not limited to the information in this plan.
- Understand how chemical fume hoods and other forms of local exhaust ventilation (e.g., a biosafety cabinet) operate and how to recognize when one is malfunctioning.
- Report all injuries, illnesses, or accidents to the laboratory supervisor.
- Report all unsafe conditions or any questions concerning the hazards associated with a procedure or any safe work practices to the laboratory supervisor or chemical hygiene officer.

1.11.2 Chemical Hazards

This section discusses different types of hazardous chemicals and how their hazards are evaluated and the control measures that can be used to minimize employee exposure. The OSHA Laboratory Standard defines a hazardous chemical as any element, chemical compound, or mixture of elements and/or compounds that is a physical hazard or a health hazard. The standard applies to all hazardous chemicals regardless of the quantity. Labeling hazardous chemicals in the laboratory is essential, as is labeling areas in the laboratory where hazardous chemicals are located. (For labeling strategies, see Appendix 1.C.)

A CHEMICAL IS CONSIDERED HAZARDOUS IF IT IS LISTED IN ANY OF THE FOLLOWING

- OSHA, 29 CFR 1910.1000 Tables Z–l through Z–3
- Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment ACGIH (latest edition)
- The Registry of Toxic Effects of Chemical Substances NIOSH (latest edition)

In addition, OSHA established a category of chemicals known as “particularly hazardous substances” in the Laboratory Standard. Particularly hazardous substances include select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity.

PARTICULARLY HAZARDOUS SUBSTANCES

- A chemical is a physical hazard if it possesses flammable, combustible, explosive, oxidizing, pyrophoric, or reactive properties or if it is an organic peroxide or compressed gas.
- A chemical is a health hazard if it produces acute or chronic health effects in exposed employees. Classes of health hazards include carcinogens; reproductive toxins; sensitizers; hepatotoxins (liver toxins); agents that act on the hematopoietic system (blood); agents that damage the lungs, skin, eyes, or mucous membranes; irritants; corrosives; neurotoxins (nerve toxins); and nephrotoxins (kidney toxins).

Many products used in the workplace are mixtures of different chemicals. In accordance with OSHA, a mixture is assumed to present the same health hazards as each component that comprises 1% or more of the mixture. A mixture is assumed to be carcinogenic if it contains a carcinogenic component in a concentration of 0.1% or more.

1.11.3 Hazard Types

Corrosives (example: household bleach) Corrosives are most often acids and bases, but do include other compounds such as phenol. Corrosives will destroy body tissue. The extent of injury depends on factors such as the type and concentration of the chemical, the route of exposure, the type of tissue contacted, and the speed used in applying emergency measures. Acids, especially in concentrated form, are most likely to cause immediate pain upon contact with tissues. Skin contact with strong bases usually goes unnoticed since immediate pain does not occur.

Irritants (examples: alcohol and xylene vapors, soaps, and detergents) Irritants are materials that cause inflammation of mucous membranes with which they come in contact. Inflammation of tissue results from exposure to concentrations far below those needed to cause corrosion. *Examples include ammonia, alkaline dusts and mists, hydrogen chloride, phosphorous chlorides, and most solvents*.

Irritants can also cause changes in the mechanics of respiration and lung function. Long-term exposure to irritants can result in increased mucous secretions and chronic bronchitis. *Examples include acetic acid, acrolein, formaldehyde, formic acid, iodine, and sulfuric acid*.

A primary irritant exerts no systemic toxic action either because the products formed on the tissue of the respiratory tract are nontoxic or because the irritant action is far in excess of any systemic toxic action. *Example includes hydrogen chloride*.

A secondary irritant's effect on mucous membranes is overshadowed by a systemic effect resulting from absorption of the chemical. *Examples include alcohol, aromatic hydrocarbon, and asphyxiant, which all have the potential to deprive tissue of oxygen, halogenated hydrocarbons, and hydrogen sulfide*.

Flammables (examples: ethanol, isopropanol, xylene) Flammable and combustible chemicals include flammable gases and liquids such as organic solvents, oils, greases, tars, oil-based paints, and lacquers. As a general rule, the lower the flash point of a liquid, the greater the fire and explosion hazard. The flash point of a liquid is the minimum temperature at which it gives off sufficient vapor to form an ignitable mixture with the air near its surface or within its containment vessel. Flammable and combustible liquids are defined by and divided into classes by the National Fire Protection Association (NFPA) based on their flash points.

CLASSES OF FLAMMABLE AND COMBUSTIBLE LIQUIDS

- Flammable liquids (class I): Liquids having flash points below 100°F (37.8°C). Flammable class I liquids are subdivided as follows:
  - Class IA: Liquids having flash points below 73°F (22.8°C) and boiling points below 100°F (37.8°C). *Flammable aerosols (spray cans) and ethyl ether are examples included in Class IA*.

- Class IB: Liquids having flash points below 73°F (22.8°C) and having boiling points at or above 100°F (37.8°C). *Examples include alcohols, acetone, hexanes, xylenes, and ethyl acetate*.
- Class IC: Liquids having flash points at or above 73°F (22.8°C) and below 100°F (37.8°C). The boiling point is not considered. *Examples include ethanethiol and 2,3-butanedione (diacetyl)*.

- Combustible liquids (classes II and III): Liquids having flash points at or above 100°F (37.8°C). Combustible liquids in classes II and III are subdivided as follows:
  - Class II: Liquids having flash points at or above 100°F (37.8°C) and below 140°F (60.0°C). *Examples include glacial acetic acid and N,N-dimethylformamide*.
  - Class IIIA: Liquids having flash points at or above 140°F (60.0°C) and below 200°F (93.4°C). *An example is 2-mercaptoethanol*.
  - Class IIIB: Liquids having flash points at or above 200°F (93.4°C). *An example is t-butyl carbamate*.

Carcinogens (examples: chloroform, formaldehyde) Carcinogens are diverse agents that cause malignant neoplasms in humans. Carcinogenic agents may be organic chemicals, inorganic chemicals, hormones, or ionizing radiation. Some carcinogens react directly with a cell's DNA, causing mutations that are incorporated into subsequent generations of that cell.

The term "select carcinogens," first coined in the OSHA Laboratory Standard, applies to those chemicals regulated as carcinogens, those strongly implicated as a cause of cancer in humans, and/or those with significant data to suggest that they could be human carcinogens.

Toxins (examples: phenol, cycloheximide, formamide) Substances of high acute toxicity include materials that may be fatal or cause damage to target organs from a single exposure or from exposures of short duration. They also include materials capable of causing intense irritation that can result in pulmonary edema (fluid and swelling in the lungs), chemical asphyxia, and systemic (body-wide) poisoning. There are several standard terms used to describe toxic effects.

TOXIC EFFECTS

- Acute poisoning is characterized by sudden and severe exposure and rapid absorption of the substance. Adverse health effects are often irreversible. *Examples include carbon monoxide and cyanide poisoning*.
- Chronic poisoning is characterized by prolonged or repeated exposure of a duration measured in days, months, or years. Health effects are often irreversible. *Examples include lead and mercury poisoning*.
- A local effect refers to an adverse health effect that takes place at the point or area of contact. The site may be skin, mucous membranes, the respiratory tract, gastrointestinal system, eyes, etc. *Examples include strong acids and alkalis*.

- Systemic effect refers to an adverse health effect that takes place at a location distant from the body's initial point of contact and presupposes absorption has taken place. *For example, arsenic affects the blood, nervous system, liver, kidneys, and skin; benzene affects bone marrow*.
- Cumulative poisons are characterized by materials that tend to build up in the body as a result of numerous chronic exposures. The effects are not seen until a critical body burden is reached. *Example includes heavy metals*.
- Substances in combination: when two or more hazardous materials are present at the same time, the resulting effect can be greater than the effect predicted based on the additive effect of the individual substances. This is called a synergistic or potentiating effect. *Example includes exposure to alcohol and chlorinated solvents or smoking and asbestos*.

FACTORS THAT AFFECT TOXICITY

- Rate of entry and route of exposure
- Age
- Previous exposure
- State of health, physical condition, and lifestyle
- Preexisting disease
- Environmental factors such as temperature and pressure
- Host factors, including genetic predisposition and sex of the exposed individual

Reproductive toxins (example: cycloheximide) Reproductive toxins are agents that affect reproductive capabilities including chromosomal mutations and produce effects on fetuses (teratogenesis). Reproductive toxins can affect both men and women. Examples of adverse reproductive health effects include birth defects, spontaneous abortion, fetal developmental damage, and infertility. Women who are (or trying to become) pregnant should consult with their physician before the start of any laboratory activity involving reproductive toxins.

Sensitizers (allergens) (example: formaldehyde) A sensitizer is a chemical that can cause an allergic reaction in normal tissue after repeated exposure to the chemical. Many of the biologicals used in laboratories are also potential sensitizers. The reaction may be as mild as a rash (allergic dermatitis) or as serious as anaphylactic shock. *Examples include chromium compounds*, *chlorinated hydrocarbons*, *epoxies*, *nickel compounds*, *toluene diisocyanate*, *and formaldehyde*.

Reactives (examples: butadiene, acetyl, benzyl alcohol) Reactive (unstable) materials are solids, liquids, and gases that in a pure state, or as commercially produced or transported, will vigorously polymerize, decompose, combine, or become self-reactive under conditions of shock, pressure, or temperature. *Examples include peroxide-forming chemicals, water-reactive chemicals, and pyrophoric materials*.

Compressed gases and cryogenics (examples: carbon dioxide gas and dry ice) Compressed gases Many laboratory operations require the use of compressed gases for analytical or instrument operations. Depending on the particular gas, there is a potential for simultaneous exposure to both mechanical and chemical hazards.

Careful procedures are necessary for handling the various compressed gases, the cylinders containing the compressed gases, regulators, or valves used to control gas flow, and the piping used to confine gases during flow.

Cryogenics Contact (even brief periods of time) with a cryogenic liquid is capable of causing tissue damage similar to that of thermal burns. Prolonged contact may result in blood clots that have potentially serious consequences. Surfaces cooled by cryogenic liquids can also cause severe damage to the skin. Gloves and eye protection (preferably a face shield) should be worn at all times when handling cryogenic liquids. Gloves should be chosen that are impervious to the fluid being handled and loose enough to be tossed off easily.

Adequate ventilation is required when using cryogenic liquids or gases of nitrogen, helium, or carbon dioxide, especially in small spaces. Oxygen may be displaced to the point that employees may experience oxygen deficiency or asphyxiation.

1.11.4 Hazard Information

1.11.4.1 SDSs and the New Globally Harmonized System (GHS) The OSHA Haz Com Standard established the minimum requirements for communicating hazards to workers. This standard is often referred to as the "worker right-to-know" standard, and it predates the OSHA Chemical Hygiene Standard by a number of years. The Haz Com Standard established that hazard communication be conveyed by proper labeling, training, and manufacturer SDSs.

During the 1992 United Nations Conference on Environment and Development (UNCED), a mandate was made to globally harmonize the chemical hazard classification system.

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS (GHS) ENTAILS THE FOLLOWING THREE STEPS

- Defining health, physical, and environmental hazards of chemicals
- Creating classification processes that use available data on chemicals for comparison with the defined hazard criteria
- Communicating hazard information, as well as protective measures, on labels and Safety Data Sheets (SDSs)

Most developed countries and chemical supply vendors have already adopted the new system, and the United States has revised its OSHA Haz Com Standard to be in sync with the new system. The following phase-in dates are required under the new Haz Com Standard:

- By December 1, 2013—Employers must train workers on the new label elements and SDS format.
- By June 1, 2015—Chemical manufacturers, importers, distributors, and employers must comply with all modified provisions of the final rule.
- By June 1, 2016—Employers must update alternative workplace labeling and hazard communication programs as necessary and provide additional worker training for new identified physical and health hazards.

1.11.4.2 Hazard Communication Standard's Laboratory Requirements Regarding Retention of Labels and SDSs These provisions require that SDSs for hazardous chemicals received with incoming shipments be maintained and made readily accessible to employees and that labels not be removed or defaced unless immediately replaced with other appropriate ones. An SDS is a technical bulletin detailing information about a hazardous chemical. Every chemical manufacturer or importer must develop or obtain an SDS for each hazardous chemical it supplies. Distributors also must provide SDSs to other distributors and commercial purchasers of their hazardous chemicals. The laboratory must provide SDSs for each hazardous chemical in the workplace.

Manufacturers may withhold certain information (such as specific chemical identities and/or amounts of its components) as proprietary on an SDS if the information is considered a trade secret. The chemical hygiene officer has a legal right to obtain this information from the manufacturer to evaluate the potential health risk if potential overexposure or adverse health effects are suspected. The SDS format must include, at a minimum, 16 defined sections, as listed as follows.

SECTIONS OF SDSs

Section 1, Identification includes product identifier, manufacturer or distributor name, address, phone number; emergency phone number, recommended use, restrictions on use.

Section 2, Hazard(s) identification includes all hazards regarding the chemical; required label elements.

Section 3, Composition/information on ingredients includes information on chemical ingredients, trade secret claims.

Section 4, First-aid measures includes important symptoms/effects, acute, delayed; required treatment.

Section 5, Fire-fighting measures lists suitable extinguishing techniques, equipment; chemical hazards from fire.

Section 6, Accidental release measures lists emergency procedures, protective equipment, proper methods of containment and cleanup.

Section 7, Handling and storage lists precautions for safe handling and storage, including incompatibilities.

Section 8, Exposure controls/personal protection lists OSHA's Permissible Exposure Limits (PELs), Threshold Limit Values (TLVs), appropriate engineering controls, personal protective equipment (PPE).

Section 9, Physical and chemical properties lists the chemical's characteristics.

Section 10, Stability and reactivity lists chemical stability and possibility of hazardous reactions.

Section 11, Toxicological information includes routes of exposure; related symptoms, acute and chronic effects, numerical measures of toxicity.

Section 12, Ecological information*

Section 13, Disposal considerations*

Section 14, Transport information*

Section 15, Regulatory information*

Section 16, Other information, includes the date of preparation or last revision.

*NOTE: Since other Agencies regulate this information, OSHA does not enforce Sections 12 through 15(29 CFR 1910.1200(g)(2)).

1.11.5 Signs and Labeling

Manufacturers are required to determine the hazardous properties of the materials they produce. This information is conveyed through SDSs and labels.

1.11.5.1 Signs Signs must be consistent with the requirements of the Hazardous Materials Transportation Act (18 USC 1801 et seq.) and with other OSHA substance-specific health standards. Signage requirements, in particular, are usually included in OSHA's substance-specific health standards (e.g., see "Use of Formaldehyde," Section 1.11.18). Prominent signs and labels of the following types shall be posted to assure immediate employee recognition and appropriate action in the event of an emergency or to signal other precautionary activity.

TYPES OF SIGNS AND LABELS

- Emergency telephone numbers of personnel/facilities, supervisors, and key laboratory employees
- Labels identifying contents of containers (including hazardous waste containers) and associated hazards
- Location signs for safety showers, eyewash stations, and other safety and first aid equipment and exits
- Warnings at areas or equipment where special or unusual hazards exist
- Areas where food consumption and storage are prohibited and are permitted
- Flammable signs on storage cabinets for flammable and combustible liquids

1.11.5.2 Labeling OSHA's stated purpose is to have labels serve only as an immediate warning and reminder that more detailed information is available elsewhere. Labels may use symbols, pictures, and/or words to present their message. There are several hazard labeling systems, including the legally required Department of Transportation (DOT) system for package labeling. However, the two most common labeling systems for laboratory containers are the NFPA system and the Hazardous Materials Information System (HMIS). Some manufacturers have also created their own systems, which usually rely heavily on pictograms (e.g., J.T. Baker SAF-T-Data System).

All of these systems (excluding DOT) use a numerical rating scale of 0–4 (no hazard to high hazard) for to represent hazard categories.

HAZARD COLORS AND CATEGORIES

- **Red for flammability hazard**
- **Blue for health hazards**
- **Yellow for reactivity hazard**
- **White for "special hazards," such as water reactive, oxidizer, and corrosive**

Under GHS and the Haz Com Standard, there are nine pictograms to convey the health, physical, and environmental hazards. The final Haz Com Standard requires eight of these pictograms, the exception being the environmental pictogram, as environmental hazards are not within OSHA's jurisdiction.

FOUR CATEGORIES OF CONTROLS INVOLVING PARTICULARLY HAZARDOUS SUBSTANCES

- Establish posted designated areas. The purpose is to ensure that proper controls are in place and that all activities involving particularly hazardous substances are confined to the designated area.
- Use containment devices (such as fume hoods, gas cabinets, glove boxes or the equivalent).
- Implement contaminated waste removal procedures.
- Establish decontamination procedures. Decontamination procedures include practicing good housekeeping by wiping down work surfaces at the end of the day and cleaning up drips, residues, and spills.

1.11.6 Safety Practices for Chemical Procurement and Transport

The chemical hygiene officer must be notified anytime a new hazardous chemical is purchased that has never been purchased before. The procurement step includes a hazard assessment of new chemicals in order to determine if they are really necessary, ensure control measures are in place to work with them, and arrange personnel training.

Examples of chemicals which should be flagged at the procurement step are FDA-controlled substances, highly toxic chemicals, cytotoxins, highly reactive chemicals, and chemicals subject to specific regulations (e.g., OSHA standards, the CDC registration as a "select toxic agent," etc.). Three common laboratory chemicals that require special safety practices and control measures are perchloric acid, hydrofluoric acid, and ethyl ether.

SAFETY PRACTICES FOR CHEMICAL PROCUREMENT

- Before receiving and using a hazardous substance, personnel must be familiar with the proper handling procedures.
- All chemicals shall be inspected periodically (at least annually) for replacement, deterioration, and container integrity.
- Storage is permitted on shelves above benches, in cabinets under benches, or in cabinets under hoods.
- Chemicals should be stored with the "date opened" clearly marked on the container.

SAFETY PRACTICES FOR DISTRIBUTING AND TRANSPORTING CHEMICALS

- Plastic/rubber bottle carriers or carts shall be used when transporting large glass bottles (1 gallon or greater) of hazardous chemicals from one location to another.
- Large bottles shall never be lifted by the lid or even by the molded ring at the top. Two hands should always be used, with one under the bottle and the other around the neck.
- Cylinders—full, empty, or otherwise—may only be transported by hand truck, chained to it firmly and capped.
- Compressed gas cylinders, whether full, empty, or being used, shall always be secured to a sturdy support by a device designed to prevent toppling.
- Cylinders shall always be capped when not in use, with the valve off when not attended.
- Cylinders containing flammable gas shall never be stored or used in the vicinity of open flames or other ignition sources or in the vicinity of cylinders containing compressed oxygen or air.

1.11.7 Basic Safety Practices

General

- No eating, drinking, or smoking and no food storage in labs.
- NEVER pipette by mouth.
- Wear closed-toed shoes (NO open-toed shoes/sandals allowed).
- No bare legs allowed in labs (wear lab coat with shorts, skirts, or dresses).
- Wear eye protection whenever there is a chance of splash or aerosol occurring from a corrosive, irritant, or toxic chemical.
- Wear thermal insulating gloves while handling very hot or cold items.
- Wear lab coats when working in labs and specimen accessioning areas.
- *Do not* wear lab coats in administrative/office areas.
- Remove gloves before leaving the lab area whenever possible. Otherwise, the “one glove rule” applies for movement between lab areas, that is, no glove on the hand used on door handles.
- *Do not* contaminate countertops, equipment, doorknobs, etc., with soiled gloves. Change gloves as necessary to avoid contamination potential.
- Restrict chemicals and reagents to the designated lab areas.
- Transport chemicals safely using carts, trays, transport buckets, etc.
- Take responsibility for keeping common-use equipment and areas clean, orderly, and stocked with the necessary supplies.
- Wash hands with soap and water before leaving the labs.

Laboratory/facility

- Keep emergency shower/eyewash areas clear of boxes, carts, etc.
- Notify a supervisor immediately if you are injured or hurt.
- Notify a supervisor immediately if there is malfunctioning equipment.
- Be familiar with the locations and use of emergency equipment (e.g., fire extinguishers, emergency shower, and emergency eyewashes).
- Maintain access to all exits.
- Clean surfaces (countertops, bench tops, hoods, and floors) of all drips and residues.

Chemicals

- Purchase only nonmercury thermometers to phase out older mercury-containing thermometers.
- Make sure all chemicals, reagents, media, and prepared solutions are clearly labeled with contents, date prepared, and initials, and type of hazard (carcinogen, flammable, poison, corrosive, etc.).
- Store incompatible chemicals separately. Use a plastic pan to separate items.
- Wipe drips and residues from containers of hazardous materials.
- Clean spilled chemicals immediately and dispose of all waste properly.
- Keep containers of hazardous chemicals closed when not in use. Use fume hoods for highly toxic chemicals and volatile carcinogens.
- *Do not* purposely smell or taste chemicals.
- When diluting acids, always add acid to the water and NOT water to the acid.

1.11.8 Safe Chemical Storage

Common storage problems in laboratories can lead to mixing of incompatible chemicals. The most serious of these is the storage of acids (especially oxidizing acids) with flammable solvents. Contact of a concentrated oxidizing acid with a flammable solvent would likely result in a fire or an explosion. This is likely a scenario in the event of an earthquake. SDSs have sections on chemical incompatibility. The container's label should also provide storage guidelines.

Hazard Classes—Chemicals should be separated according to the following categories, because this allows storage according to hazard class.

SOLVENTS

- Solvents include nonhalogenated solvents that are flammable/combustible liquids. Examples include acetone, alcohols, ethers, benzene, hexane, xylenes, ethyl acetate, tetrahydrofuran, dioxane, and DMSO.
- Solvents also include halogenated solvents that are not flammable/combustible liquids, but are often toxins and/or carcinogens. Examples include chloroform and methylene chloride.
- Store in approved safety cans or cabinets.
- Segregate from oxidizing acids and oxidizers.
- Keep away from any source of ignition: heat, sparks, or open flames.

INORGANIC ACIDS

Examples include nitric, sulfuric, hydrochloric, and phosphoric acids.

- Segregate acids from chemicals that could generate toxic or flammable gases upon contact, such as sodium cyanide, iron sulfide, calcium carbide, etc.
- Segregate acids from bases.

ORGANIC ACIDS

Examples include acetic, formic, oxalic, and benzoic acids. (Note: Glacial acetic acid is handled as a flammable liquid.)

- Segregate acids from active metals such as sodium, potassium, magnesium, etc.
- Segregate oxidizing acids from organic acids, flammable, and combustible materials.
- Segregate acids from chemicals that could generate toxic or flammable gases upon contact, such as sodium cyanide, iron sulfide, calcium carbide, etc.
- Segregate acids from bases.

BASES

Examples include sodium hydroxide, ammonium hydroxide.

- Segregate bases from acids, metals, explosives, organic peroxides, and easily ignitable materials.

OXIDIZERS

Examples include ≥70% nitric acid, bromine, ammonium persulfate, and ≥30% hydrogen peroxide.

- Store in a cool, dry place.
- Keep away from combustible and flammable materials.
- Keep away from reducing agents such as zinc, alkali metals, and formic acid.

POISONS (TOXINS AND CARCINOGENS)

- Store according to the nature of the chemical, using appropriate security where necessary. Ensure that caps and lids on all chemical containers are tightly closed to prevent evaporation of contents.
- Store all hazardous liquid chemicals in secondary containers that are chemically resistant. Plastic trays provide good containment.

EXPLOSIVES AND UNSTABLE REACTIVES

- Store in flammable storage cabinets.

CYANIDES

- Segregate from acids and oxidizers. They are water-reactive chemicals.
- Make certain that a class D fire extinguisher is available in case of fire.
- They are pyrophoric substances (materials that will react with the air to ignite when exposed, e.g., white phosphorus.)
- They are light-sensitive chemicals and peroxide-forming chemicals.
- Store in airtight containers in a dark, cool, and dry place.
- Periodically test for the presence of peroxides and watch for crystal formation, deterioration, etc. on older bottles.

1.11.9 Storage Basics

Observe the following general storage guidelines and know the properties of the chemicals used:

- Use flammable storage cabinets to store flammable liquids.
- Install Plexiglas lips or use equivalent means to prevent materials from falling off storage shelves.
- Limit the amount of chemicals stored to the minimum required.
- Be aware that squeeze bottles and Nalgene bottles have varying resistances to different chemicals depending on the components of the materials.
- Label all containers (squeeze bottles and Nalgene bottles) to which hazardous materials are transferred with the identity of the substance and its hazards.
- Use approved corrosive storage cabinets (constructed of chemically resistant components) for storing acids and bases.
- Avoid exposure of chemicals to heat or direct sunlight.
- *Do not* store chemicals in refrigerators used for food storage. Refrigerators used for storing either chemicals or food must be appropriately labeled.
- Approved refrigerators and freezers are required if used for storing flammable liquids. Do not store ethanol in refrigerators unless they are approved for flammable storage.

1.11.10 Glassware Handling

- No chipped or cracked glassware shall be used in the laboratory.
- When inserting glass into rubber tubing or stoppers, the glass shall be lubricated with glycerin before inserting and proper procedures shall be used.
- Laboratory glassware, or “borosilicate” glass, is known as Pyrex or Kimax brand. Glassware of any other type cannot be exposed to thermal shocks without breaking and should not be used in applications involving heat or cold.

- Consider purchasing plastic-coated Dewar flasks and other glassware that is used in vacuum applications.
- Broken glassware should not be picked up directly with the hands. Mechanical means, such as tongs, forceps, or a brush and dustpan, are to be utilized when cleaning up broken glass.
- Dispose of glassware in designated glass containers.

1.11.11 Heat and Chemicals

- Explosion-proof hot plates or heating mantles shall be used when heating chemicals.
- When heating organic liquids, a hot water bath system (beaker of water on hot plate) shall be used.
- Never place any equipment that is wet with organic solvents, or use flammable solvents in or near drying ovens.
- Watch ignition sources around flammable materials.

1.11.12 Electrical Safety

- Never handle any electrical equipment while wet (with wet hands or while standing on a wet floor).
- Watch ignition sources around flammable materials.
- All electrical equipment should be equipped with three-prong plugs. No 3-to-2 adapters may be used.
- Installation of proper plugs, as well as frayed cord replacement, shall be performed under the direction of Facilities personnel only. Laboratory personnel may *not* attempt any repairs on electrical equipment.
- Electrical equipment shall be checked routinely for frayed cords or other possible hazards. Damage shall be reported immediately.
- Check with facilities personnel before ordering and installing new equipment. There are amperage and voltage considerations that must have input from facilities personnel.
- No "octopus" connectors may be used in the laboratory. Each circuit (which may be represented by roughly 1–5 or so different outlet locations) has a limit that cannot be extended by just adding more extensions to plug-in equipment.
- Electrical cords shall be kept out of the vicinity of heat, open flame, or near any material which may be spilled.
- Analytical instruments and computers must be plugged into a surge protector.
- Ground fault circuit protection shall be available for all circuits in the vicinity of lab sinks.

1.11.13 Personal Protective Equipment

PPE includes chemically resistant gloves, eyewear, footwear, coveralls, and respiratory protection. PPE shall be selected on the basis of the hazards present, the type of materials used, and the manner in which they will be handled. Line managers are responsible for

ensuring that hazard assessments are performed prior to selecting PPE and that employees use PPE properly. Employees must be trained in the uses and limitations of PPE.

Remove all PPE prior to leaving the work area to prevent the spread of hazardous materials to uncontrolled areas. Normally, disposable PPE used in laboratory settings (such as gloves, Tyvek coveralls, and booties) should be disposed as hazardous waste, unless the contaminated material does not require disposal as hazardous waste.

1.11.13.1 Lab Coats and Gowns Designated lab coats shall be worn when working in the lab and accessioning areas. Lab coats are only to be worn in labs or when moving from one lab area to another; they may *not* be worn in the administrative or office areas.

1.11.13.2 Eye Protection

- Safety glasses are required to be worn when working in the lab and accessioning areas.
- Safety glasses must have side shields and meet the ANSI Z87.1 (1989) standard for impact resistance.
- Safety glasses must be supplemented with goggles and/or face shields when there is a likelihood of splashed chemicals or flying particles (e.g., when pouring or mixing chemicals and handling cryogens).
- Splash goggles and face shields are not substitutes for safety glasses in terms of impact resistance. It may be necessary to wear both together.
- Wear eye protection whenever there is a chance of splash or aerosol occurring from a corrosive, irritant, and/or toxic chemical.

1.11.13.3 Gloves

- Protective gloves must be used whenever handling anything potentially hazardous to the skin. This includes hazardous chemicals, broken glass and hot objects, cryogenics, etc.
- Gloves shall be inspected before use; reusable rubber gloves (used in dishwashing applications) shall be washed before removal, whether or not they appear to be contaminated.
- The proper type of protection depends on the material being handled. In the case of hazardous chemicals, it may be necessary to consult glove vendor selection charts to determine the correct glove material.
- No single glove material provides universal protection against all chemical agents. Gloves must be selected on the basis of their chemical resistance to the material(s) being handled, their suitability for the procedures being conducted, and their resistance to wear and temperature extremes.
- Gloves should be removed before leaving lab areas whenever possible. Otherwise, the "one glove rule" applies for movement between lab areas, that is, no glove on the hand used on door handles. Do not contaminate countertops, equipment, doorknobs, etc., with soiled gloves. Change gloves as necessary to avoid contamination potential.

1.11.13.4 Other Safety Measures

- Bare feet, sandals, and open-toed or cloth shoes are *not* allowed in the laboratory. Safety shoes must be worn by personnel in positions in which a foot injury may occur, for example, in some facilities staff activities, in construction zones, etc.

- Respirators should not be needed in normal laboratory settings. Therefore, use of respirators in the laboratory would be an unusual situation requiring a specific evaluation. The chemical hygiene officer would need to evaluate the anticipated exposures and prescribe the appropriate equipment for such a situation. All respirator users must be medically qualified, trained, and fit tested to wear the respiratory protection equipment.

1.11.14 Engineering Control Measures

- In order to protect employees from chemical exposures during handling and use, the laboratory includes controls and protective equipment that are designed to provide protection from injury.
- Engineering controls such as ventilation and lab hoods are the most effective means for minimizing chemical exposures and, therefore, are preferred to administrative controls or PPE.
- The laboratory is equipped with emergency eyewashes, safety showers, and fire suppression equipment.

1.11.15 Ventilation

General laboratory processes require a level of ventilation depending on the chemical and equipment used. The following describes different types of ventilation for general cytogenetic laboratories.

General ventilation

- The general design of the laboratory provides dilution ventilation; however, the laboratory does not rely upon it solely for protection from hazardous substances exposure.
- The general ventilation serves to assure an adequate supply of makeup air to the fume hoods and to generally ventilate relatively less hazardous substances used in benchtop procedures.
- The general ventilation in the laboratory also assures a negative pressure in the laboratory relative to other occupied areas of the facility to maintain control over passive migration of volatile substances into less effectively ventilated spaces.

Fume hoods

- Chemical fume hoods are used to prevent harmful exposure to hazardous substances.
- Lab hoods are designed and maintained so as to draw air inward at an average linear face velocity of 100 feet per minute (fpm) with a minimum of 70 feet per minute in any one measurement point. Fume hoods should have movable sashes either fully opened or closed to a marked position which achieves this rate of airflow for control of most chemicals.
- Lab hoods are recertified at least annually. The date of the inspection and the tested velocity are posted on the front of the fume hood.
- Each hood has a continuous monitoring device to indicate that the air is flowing into the exhaust system during operation.

- When flammable gases or liquids are used or when combustible liquids are heated above their flash points, the hood sash must remain open so sufficient airflow is maintained to prevent explosions.
- Exhaust stacks are designed and located to preclude recirculation of laboratory hood emissions within the building.

Biological safety cabinets

- Biological safety (biosafety) cabinets are used to prevent harmful exposures to infectious agents, other biohazardous materials, and toxic powders.
- The biological safety cabinet shall be based on the biosafety level (levels 1–4) needed for the specific hazards.
- The chosen cabinet shall meet the required airflow requirements pursuant to the NIH and CDC *Primary Containment of Biohazards: Selection, Installation and Use of Biological Safety Cabinets*, 1995. (For classes of safety hoods, see Chapter 2.)

1.11.16 Safety Equipment (Showers, Eyewashes, Fire Extinguishers)

Showers and eyewashes

- Per OSHA: Plumbed or self-contained eyewash or eye/facewash equipment shall be provided at all work areas where the eyes of an employee may come into contact with a substance which can cause corrosion, severe irritation, or permanent tissue damage or which is toxic by absorption.
- Per OSHA: An emergency shower shall be provided at all work areas where areas of the body may come into contact with a substance which is corrosive or severely irritating to the skin or which is toxic by skin absorption.
- Access to all emergency equipment including eyewashes must be kept free from blockage or barriers at all times.
- The equipment is tested at least monthly to ensure the flow rate is substantially copious and the eyewash founts meet in the center; per ANSI, the equipment should be tested weekly.

Fire extinguishers

- The building should be equipped with both fixed and portable fire extinguishers. The fixed system includes a sprinkler system meeting applicable building and fire code provisions. Portable fire extinguishers should be located throughout the building at visible and accessible locations.
- Fire extinguishers shall be kept unobstructed and available for immediate use at all times.
- All employees are authorized to use fire extinguishers. Employee training is provided initially and periodically and covers proper use and limitations of such devices.
- Portable fire extinguishers are visually inspected monthly. Annual inspections are performed by a qualified outside contractor.
- Fires that cannot be controlled by portable fire extinguishers (or become structural fires) are responded to by immediate evacuation, activation of the fire alarm, overhead paging system announcements, and coordination with the Fire Department.

1.11.17 Exposure Limits and Monitoring

Occupational exposure limits

- Most hazardous chemicals have legal occupational exposure limits that represent air concentrations in the breathing zone of the worker, which is measured at the lapel level during actual work tasks.
- Examples of substances where skin absorption may be a significant factor include pesticides, carbon disulfide, carbon tetrachloride, dioxane, methanol, acetonitrile, mercury, thallium compounds, xylene, and hydrogen cyanide.
- The term "gas" applies to a substance that is in the gaseous state at room temperature and pressure. A "vapor" is the gaseous phase of a material that is ordinarily a solid or a liquid at room temperature and pressure. The term "fume" is often used to mean vapor, but fume is actually molten metal in aerosol form (e.g., as produced in welding operations).
- When considering the toxicity of gases and vapors, the solubility of the substance is a key factor. Highly soluble materials, like ammonia, irritate the upper respiratory tract. Relatively insoluble materials, like nitrogen dioxide, penetrate deep into the lung. Fat-soluble materials, like pesticides, tend to have longer residence times in the body and be cumulative poisons.
- An aerosol is composed of solid or liquid particles of microscopic size dispersed in a gaseous medium. For a proper assessment of the toxic hazard, the size of the aerosol's particles must be determined. Particles above 10 μm tend to deposit in the nose and other areas of the upper respiratory tract. Below 10 μm particles enter and are deposited in the lungs and therefore referred to as "respirable." Very small particles (<0.2 μm) are generally not deposited but exhaled.

Exposure monitoring

- Exposure monitoring may be conducted as part of a hazard assessment administered by the chemical hygiene officer, an industrial hygienist, and/or some other Environmental Health and Safety (EH&S) professionals.
- Hazard assessments are conducted for operations involving the use of particularly hazardous substances, unstable/reactive compounds, and chemicals regulated by OSHA substance-specific standards and for other chemicals and operations as deemed appropriate.
- Operations and materials may also be assessed in response to a concern expressed by an employee or supervisor.

1.11.18 Use of Formaldehyde

- Formaldehyde is commonly used as formalin, which is a mixture of 30–50% (usually 37% formaldehyde) and 10–20% methyl alcohol in water. Another common use is buffered formalin, which is 4% formaldehyde (or paraformaldehyde) in buffer.
- Formaldehyde readily gives off irritating vapors with a strong odor. It is highly irritating to the upper respiratory track and eyes. It is also a skin irritant and a skin and respiratory tract sensitizer (allergen). It is also a regulated carcinogen.

- The 8 hour occupational exposure limit is 0.75 ppm (averaged over the 8 hours), and the 15 minute limit is 2.0 ppm. Without a fume hood, it is easy to become overexposed.
- The OSHA Formaldehyde Standard requires that affected employees receive information and training on formaldehyde's hazards and on safe handling practices. This training is included as part of Chemical Hygiene Training.
- Provisions of the Formaldehyde Standard require that employees wear protective eyewear and gloves for potential contact of the eyes and skin with liquids containing 1% or more of formaldehyde. (Wear nitrile gloves and not latex.)

Areas using formaldehyde shall have signage posted bearing the words:

DANGER

FORMALDEHYDE IS AN IRRITANT AND POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

- The employer shall conduct initial and periodic air monitoring of employees who may be exposed at or above the action level of 0.5 ppm averaged over an 8 hour day (or at or above 2 ppm for a 15 minute average time period).
- The employer shall assure that all employees who are assigned to work in places where there is exposure to formaldehyde receive training at least annually.
- The employer is to make medical surveillance available for employees who develop signs and symptoms of overexposures.

1.11.19 Spills, Injuries, and Fires

The laboratory's EAP will cover general and specific emergencies and the procedures for them. The following emergency procedure for spills, injuries, and other accidents in the laboratory are included as a required element of this Chemical Hygiene Plan.

1.11.19.1 Spills Any large chemical spill or unusual occurrence that presents a potential overexposure, fire, explosion, or other hazardous condition shall be responded to by immediate evacuation and notification of the Fire Department and the contracted emergency response company.

Workers involved in a spill or odor-causing incident (spill, machine problem, etc.) should quickly assess the situation. They should assist injured and/or contaminated persons first. Then, they should contain the spill and/or turn off affected equipment only if it is safe to do so. *Do not* proceed to clean up large spills of toxic, reactive, caustic, or flammable materials without assistance and first notifying the chemical hygiene officer or safety officer. These chemicals require the responder to wear a self-contained breathing apparatus. If the lab is unable to handle these spills directly, then the response is restricted to vacating

and containing the area. If outside assistance is needed, the company's hazardous waste vendor is notified.

Small nonvolatile chemical spills generally do not constitute a laboratory emergency. They are easily mopped up, absorbed by paper, spill pillows, rags, or some other absorbent material. The used absorbent material (including any contaminated gloves) is bagged, labeled, and placed on one of the yellow hazardous waste carts (or directly into waste drums) for management according to proper hazardous waste management procedures.

1.11.19.2 Injuries The general procedure for all emergencies is for any employee to first report the incident, however minor, to a laboratory supervisor. In a medical emergency, the supervisor should call 911; if a supervisor is not individually available, any employee should call 911.

The following procedures govern further responses to specific types of incidents:

TOXIC CHEMICAL EXPOSURE

Each employee must be familiar with the hazards of all of the chemicals they work with or work near in the laboratory by consulting the SDS. If a significant exposure occurs, immediate medical attention shall be summoned.

CHEMICAL BURNS

Chemical burns of the eyes or skin shall be flushed with copious amounts of water (emergency eyewash and safety shower) for at least 15 minutes. If the eyes are affected, they shall be flushed at the nearest eyewash station, holding both eyelids away from the eyeball and rolling the eyes. Follow up with medical attention.

THERMAL BURNS

Thermal burns of the skin shall be treated by applying large amounts of cold water or burn treatment cool packs/gels. If clothes catch fire, employees are trained to drop to the floor and roll to smother the flame or flood with water at the emergency shower. Immediate medical attention shall be summoned.

INGESTION OF CHEMICALS

Chemical ingestion shall be treated by flushing out the mouth and mucous membranes with water and seeking emergency medical assistance immediately.

1.11.19.3 Fires If the fire is small, sound an internal alarm to warn other employees of the danger. This may be done by overhead intercom announcements or even by having assigned persons shout the word "fire" throughout all areas. Next, secure the area, shutting the doors. Then attempt to extinguish the fire, only if you are comfortable in doing so. The appropriate type of fire extinguisher for the fire involved shall be used.

All employees except for those using the fire extinguishers must evacuate the building and proceed to the assembly area in the front of the building. No employee may reenter the

building until an "ALL CLEAR" is given by the Fire Department or some other authority. Small fires may not trigger the alarm (or the sprinkler system), in which case someone needs to activate an alarm pull station or actually call the Fire Department at 911 if they are needed. Employees must report any fire extinguisher use immediately to a laboratory supervisor to ensure the extinguisher is properly recharged for future use.

1.11.20 Chemical ("Hazardous") Waste Handling

Most chemical wastes generated by laboratory are presumed to be hazardous unless characterized as nonhazardous by knowledge or testing. The accumulation, storage, and disposal of all hazardous waste shall be supervised by the chemical hygiene officer.

Discharge to the sewer of most chemicals is prohibited. This includes rinsing of "empty" containers and deliberate efforts to dilute chemicals to less concentrated amounts. Only media, pH-neutral buffers, inorganic salt solutions without metals, detergents, and household bleach may be disposed down the drain. The following are *not* allowed down the drain:

- Flammables (even ethanol and isopropanol if >20%)
- Reactives (e.g., solutions with sodium azide)
- Unused waste phenolic disinfectants (e.g., LpH, Vesphene)
- Metal solutions (including copper sulfate algicides)
- Organics, stains, toxins, mutagens, etc.
- Corrosives (<pH 5 or >pH 9)

BASIC RULES FOR CHEMICAL WASTE HANDLING

- *Do not* triple rinse empty containers. Place empty containers that have a hazardous residue (e.g., empty acid and phenol bottles) with other collected hazardous waste.
- Empty bottles of solvents, alcohols, etc. (if no larger than 5 gallons in size) can be tossed in the glass waste container or regular garbage. Deface the label and remove the lid first to prevent pressure buildup of flammable vapors.
- *Do not* use the fume hood to evaporate unwanted chemicals. "Airing out" of empty bottles is okay. But no indefinite off-gassing is permitted (i.e., do not leave empty bottles in the hoods for days on end.)
- Dispose of glass in marked cardboard boxes designated for that purpose (unless contaminated with a biological material).
- Ensure all chemical wastes are labeled with the words "Hazardous Waste" and the names and approximate percentages of constituents, the start and finish dates, and hazard information (including those on lab benches).
- The collection container shall be compatible with the waste it contains and not mixed with other incompatible wastes.
- The waste collection container must have a lid. Do not use a flask or beaker to collect waste. Funnels can be used *only* during liquid transfers and not left in the container indefinitely. Containers must be kept closed when not in use.

- Place all used metal sharps (including razor blades) in green (nonbiohazard) sharps containers. Discard container as nonregulated sharps when the container reaches a capacity of 2/3 full or more.
- Place used plastic and glass sharps in "broken/used glass" cardboard boxes or directly into the trash.
- Use secondary containment (plastic trays) for all liquid hazardous waste and all bagged solid hazardous waste debris (e.g., from a chemical spill cleanup).

1.11.21 Training and Employee Information

1.11.21.1 Training Chemical Hygiene Training shall be provided to every employee who has any work assignment in any lab area. This includes dishwashers, shipping and receiving clerks, etc. Ideally, the training should be provided upon initial assignment to the laboratory area(s) or as soon as practical. In addition, supplemental and refresher training is often needed to address new operations involving potential exposures to new hazardous substances.

TRAINING MUST INCLUDE THE FOLLOWING INFORMATION

- OSHA Chemical Hygiene Standard and the laboratory's specific Chemical Hygiene Plan, including the name of the chemical hygiene officer.
- Location and availability of the Chemical Hygiene Plan and the SDSs.
- Rights and responsibilities of the person being trained and whom to ask when there are questions.
- Hazardous chemicals the laboratory uses, what their hazards are, and the signs and symptoms associated with exposures to these chemicals.
- "Particularly hazardous chemicals" including "select carcinogens," sensitizers, and reproductive toxins.
- Basic and specific work practices as a means of controlling chemical exposures and accidents. This includes labeling, transport and storage.
- Availability, use, and limitations of personal protective equipment (e.g., gloves, eye protection, lab coats).
- Types of engineering controls, how they work, and how to know when they are not working.
- Locations and use of safety equipment and emergency response procedures specific to the laboratory.
- Occupational exposure limits, air monitoring, and the formaldehyde substance-specific OSHA standard.
- Waste handling.
- Availability and requirements of medical consultations and surveillance.

1.11.21.2 Employee Information Employee information comes by training, by asking a knowledgeable person, by reading written resources, and by searching for online computer Internet information.

1.11.21.3 Reproductive Health Concerns Whether male or female, it is important to know *before* conception about workplace reproductive hazards, such as chemical and ionizing radiation, because critical cell development occurs during the first 3 months of pregnancy. Chemical exposures should be limited for men and women who are planning conception and for pregnant women and their fetuses.

Awareness of the types of hazards and where they may be encountered is important. Laboratories should consider, at a minimum, the following chemicals known to cause reproductive effects when inhaled.

CHEMICALS KNOWN TO CAUSE REPRODUCTIVE EFFECTS

- Carbon disulfide
- Lead and lead compounds
- Dinitrobenzene
- Mercury and mercury compounds
- Ethylene glycol monoethyl ether
- Ethylene glycol monomethyl ether
- Toluene
- Ethylene oxide

A confidential consultation with an EH&S team member can help an employee identify reproductive hazards and provide guidance for making informed choices about work activities.

1.11.22 Medical Consultations and Surveillance

All employees who work with hazardous chemicals in the laboratory shall have an opportunity to receive free medical consultations, including any follow-up examinations which the examining physician determines to be necessary.

Generally, properly maintained chemical fume hoods and other ventilation systems are designed to minimize chemical exposures and to meet the applicable permissible exposure levels. Exposure monitoring may be performed to verify exposure control or as required by regulation.

1.11.23 Recordkeeping

To assure implementation of the Chemical Hygiene Plan and proper documentation for safety performance, records shall be maintained in conjunction with the IIPP.

RECORDS FOR IIPP

- An incident report must be filed for injuries/illnesses, exposure incidents, and other accidents and spills, no matter how insignificant it may initially appear. Any injury or illness triggers a report and an investigation of the incident. Accident and injury and illness investigation reports should be conducted, documented, and retained as part of the company's IIPP.
- Chemical Hygiene Plan records shall be maintained to document the status of fume hoods, emergency safety showers, eyewashes, fire extinguishers, and any other safety equipment.
- Inventory and usage records for high-risk substances shall be maintained, which include the amounts of materials on hand and used and the names of the workers involved.
- Medical records (examinations, consultations, exposure monitoring results, etc.) shall be maintained in accordance with the OSHA access standard (8 CCR §3204). Such records shall be maintained for duration of employment plus 30 years, as required. Employees are provided access as provided in the standard.
- Training records, including rosters, agendas, training materials, acknowledgment forms, etc.

1.12 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) INCIDENT PLAN

HIPAA is the federal Health Insurance Portability and Accountability Act of 1996. The primary goal of the law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information (protected health information (PHI)), and help the healthcare industry control administrative costs. PHI is any information about health status, provision of healthcare, or payment for healthcare that can be linked to a specific individual.

This document describes a procedure for the identification, reporting, and ensuring timely response to a HIPAA incident of any kind. This document applies to all departments that handle PHI including electronic PHI (ePHI).

1.12.1 Definitions

- **Protected Health Information Privacy Rule** (Ref: 45 CFR Part 160). The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "PHI." Individually identifiable health information is information, including demographic data, that relates to:
  - The individual's past, present, or future physical or mental health or condition.
  - The provision of healthcare to the individual.

- The past, present, or future payment for the provision of healthcare to the individual and that identifies the individual for which there is a reasonable basis to believe it can be used to identify the individual.

Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security number). The Privacy Rule excludes from PHI employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g.

- **De-Identified Health Information** (Ref: 45 CFR 164.514a). There are no restrictions on the use or disclosure of de-identified health information. De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information:
  - A formal determination by a qualified statistician.
  - The removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.
- **Security incident** (Ref: 45 CFR § 164.304). A security incident is defined as:
  - Attempted unauthorized access, use, disclosure, modification, or destruction of information.
  - Attempted interference with information system.
  - Loss of device or media with sensitive data or information.
- **HIPAA breach** (Ref: 45 CFR § 164.402). The following terms have the following meanings:
  - Breach means the acquisition, access, use, or disclosure of PHI in a manner which compromises the security or privacy of the PHI.
  - Breach excludes:
    - Any unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of a covered entity or a business associate.
    - Any inadvertent disclosure by a person who is authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity or business associate or organized healthcare arrangement.
    - A disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

An acquisition, access, use, or disclosure of PHI is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the following factors:

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of reidentification.
- The unauthorized person who used the PHI or to whom the disclosure was made.
- Whether the PHI was actually acquired or viewed.
- The extent to which the risk to the PHI has been mitigated.

- **Individual identifying records**—Data are "individually identifiable" if they include any of the 18 types of identifiers for an individual or for the individual's employer or family member or if the provider or researcher is aware that the information could be used, either alone or in combination with other information, to identify an individual.

INDIVIDUAL IDENTIFIERS

- Name
- Address
- All elements (except years) of dates related to an individual (including birth date, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- FAX number
- Email address
- Social Security number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate/license number
- Device identifiers or serial numbers
- Web URLs
- IP address
- Biometric identifiers, including fingerprints or voice prints
- Full-face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

- **PHI incident—**A security breach or an attempted "hack" in the laboratory's information network, paper or electronic. PHI incidents can originate in any laboratory department.
- **Business associate—**With certain exceptions, a person or entity that:
  - Creates, receives, maintains, or transmits PHI for a function or activity regulated by the Privacy Rule.
  - Provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for the laboratory.

A business associate includes a personal health record vendor, health information organization, and an E-prescribing gateway or other organization that provides data transmission of PHI to a covered entity and requires access to such PHI on a routine basis. A business associate is also a subcontractor that creates, receives, maintains, or transmits PHI on behalf of a business associate.

- **Business associate agreement**—A covered entity's written agreement with its business associate, setting forth the business associate's obligations related to the covered entity's PHI.

HIPAA PROCEDURE

1. An incident response team should be formed with the following people or representatives from the following departments:
   - Chief Compliance Office
   - Quality Assurance (QA) Department
   - Legal Department
   - The department in which the incident occurred
   - Information Technology (IT) Department (if the incident was electronic)
   - Security Officer or his designee
2. All personnel must report a PHI incident to the Chief Compliance Officer.
3. The incident report will be logged as a Customer Report Incident (CRI) log.
4. The QA team will investigate the problem.
5. The incident response team will review the investigation and determine if it is reportable to the individual whose information has been compromised.
6. The incident response team will further evaluate whether the incident is reportable to Health and Human Services, or any other appropriate authorities, and/or the media.
7. Training will be included as part of the corrective action, if deemed necessary.

1.12.2 HHS Breach Notification Requirements

Following a breach of unsecured PHI, the laboratory must provide notification of the breach to the affected individuals, the Health and Human Services (HHS) Secretary, and, in certain circumstances, to the media. In addition, business associates must notify the laboratory if a breach occurs at or by the business associate.

- **Individual notice—**The laboratory must notify affected individuals following the discovery of a breach of unsecured PHI. The laboratory must provide this individual notice in written form by first-class mail or, alternatively, by e-mail if the affected individual has agreed to receive such notices electronically. The laboratory must include a toll-free phone number that remains active for at least 90 days so individuals can learn if their information was involved in the breach.

These individual notifications must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include, to the extent possible:

- A brief description of the breach
- A description of the types of information that were involved in the breach
- The steps affected individuals should take to protect themselves from potential harm
- A brief description of what the covered entity is doing to investigate the breach, mitigate the harm, and prevent further breaches
- A contact information for the covered entity (or business associate, as applicable)

With respect to a breach at or by a business associate, while the laboratory is ultimately responsible for ensuring individuals are notified, the laboratory may delegate the responsibility of providing individual notices to the business associate:

- **Media notice—**If the laboratory experiences a breach affecting more than 500 residents of a state or jurisdiction, then, in addition to notifying the affected individuals, the laboratory is required to provide notice to prominent media outlets serving the state or jurisdiction. The laboratory will likely provide this notification in the form of a press release to appropriate media outlets serving the affected area. Like individual notice, this media notification must be provided without unreasonable delay and in no case later than 60 days following the discovery of a breach and must include the same information required for the individual notice.
- **Notice to the HHS Secretary—**In addition to notifying affected individuals and the media (where appropriate), the laboratory must notify the Secretary of breaches of unsecured protected health information. The laboratory will notify the Secretary by visiting the HHS website http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html and filling out and electronically submitting a breach report form. If a breach affects 500 or more individuals, covered entities must notify the Secretary without unreasonable delay and in no case later than 60 days following a breach. If, however, a breach affects fewer than 500 individuals, the laboratory may notify the Secretary of such breaches on an annual basis.
- **Notification by a business associate**—If a breach of unsecured PHI occurs at or by a business associate, the business associate must notify the laboratory following the discovery of the breach.

APPENDIX 1.A

OSHA's Form 300 (Rev. 01/2004)

Log of Work-Related Injuries and Illnesses

Attention: This form contains information relating to employee health and must be used in a manner that protects the confidentiality of employees to the extent possible while the information is being used for occupational safety and health purposes.

Year _____

U.S. Department of Labor
Occupational Safety and Health Administration

Form approved OMB no. 1218-0176

You must record information about every work-related injury or illness that involves loss of consciousness, restricted work activity or job transfer, days away from work, or medical treatment beyond first aid. You must also record significant work-related injuries and illnesses that are diagnosed by a physician or licensed health care professional. You must also record work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR 1904.8 through 1904.12. Feel free to use two lines for a single case if you need to. You must complete an injury and illness incident report (OSHA Form 301) or equivalent form for each injury or illness recorded on this form. If you're not sure whether a case is recordable, call your local OSHA office for help.

Establishment name _____

City _____ State _____

Identify the person				Describe the case		Classify the case											
						CHECK ONLY ONE box for each case based on the most serious outcome for that case:				Enter the number of days the injured or ill worker was:		Check the "injury" column or choose one type of illness:					
(A) Case No.	(B) Employee's Name	(C) Job Title (e.g., Welder)	(D) Date of injury or onset of illness (mo./day)	(E) Where the event occurred (e.g. Loading dock north end)	(F) Describe injury or illness, parts of body affected, and object/substance that directly injured or made person ill (e.g. Second degree burns on right forearm from acetylene torch)	Death (G)	Days away from work (H)	Remained at work: Job transfer or restriction (I)	Remained at work: Other record-able cases (J)	Away From Work (days) (K)	On job transfer or restriction (days) (L)	(M) Injury (1)	Skin Disorder (2)	Respiratory Condition (3)	Poisoning (4)	Hearing Loss (5)	All other illnesses (6)
					Page totals	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*

Be sure to transfer these totals to the Summary page (Form 300A) before you post it.

	Injury	Skin Disorder	Respiratory Condition	Poisoning	Hearing Loss	All other illnesses
	(1)	(2)	(3)	(4)	(5)	(6)

Public reporting burden for this collection of information is estimated to average 14 minutes per response, including time to review the instruction, search and gather the data needed, and complete and review the collection of information. Persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. If you have any comments about these estimates or any aspects of this data collection, contact: US Department of Labor, OSHA Office of Statistics, Room N-3644, 200 Constitution Ave, NW, Washington, DC 20210. Do not send the completed forms to this office.

APPENDIX 1.B

OSHA's Form 300A (Rev. 01/2004)

Summary of Work-Related Injuries and Illnesses

Year _____

U.S. Department of Labor
Occupational Safety and Health Administration

Form approved OMB no. 1218-0176

All establishments covered by Part 1904 must complete this Summary page, even if no injuries or illnesses occurred during the year. Remember to review the Log to verify that the entries are complete

Using the Log, count the individual entries you made for each category. Then write the totals below, making sure you've added the entries from every page of the log. If you had no cases write "0."

Employees former employees, and their representatives have the right to review the OSHA Form 300 in its entirety. They also have limited access to the OSHA Form 301 or its equivalent. See 29 CFR 1904.35, in OSHA's Recordkeeping rule, for further details on the access provisions for these forms.

Number of Cases

Total number of deaths	Total number of cases with days away from work	Total number of cases with job transfer or restriction	Total number of other recordable cases
0	0	0	0
(G)	(H)	(I)	(J)

Number of Days

Total number of days away from work	Total number of days of job transfer or restriction
0	0
(K)	(L)

Injury and Illness Types

Total number of… (M)			
(1) Injury	0	(4) Poisoning	0
(2) Skin Disorder	0	(5) Hearing Loss	0
(3) Respiratory Condition	0	(6) All Other Illnesses	0

Establishment information

Your establishment name _____

Street _____

City _____ State _____ Zip _____

Industry description (e.g., Manufacture of motor truck trailers)

_____

Standard Industrial Classification (SIC), if known (e.g., SIC 3715)

___ ___ ___ ___

OR North American Industrial Classification (NAICS), if known (e.g., 336212)

___ ___ ___ ___ ___ ___

Employment information

Annual average number of employees _____

Total hours worked by all employees last year _____

Sign here

Knowingly falsifying this document may result in a fine.

I certify that I have examined this document and that to the best of my knowledge the entries are true, accurate, and complete.

_____ Company executive

_____ Title

_____ Phone

_____ Date

Post this Summary page from February 1 to April 30 of the year following the year covered by the form

APPENDIX 1.C: INFORMATION ON HMIS AND NFPA LABELING SYSTEMS USED IN LABORATORIES

Overview

Two important chemical hazard labeling systems used in healthcare facilities are the Hazardous Materials Identification System (HMIS®) and the NFPA 704 system. At first glance, the HMIS® and NFPA labeling systems appear quite similar; both have four sections colored blue, red, yellow, and white. Despite their similarities, the two systems are not identical and each system serves a specific purpose.

HMIS® and NFPA labeling systems

- HMIS® is a complete system designed to aid employers and their employees in day-to-day compliance with OSHA's Hazard Communication Standard. It includes hazard evaluations; a rating system for acute and chronic health, flammability, and physical hazards; labels providing at-a-glance information on the hazards and PPE; employee training; and a written compliance program. HMIS was developed by the National Paint and Coatings Association (NPCA).
- NFPA 704 system is a fire protection hazard warning system designed to provide rapid, clear information to emergency responders on materials under conditions of fire, chemical spill, or other emergency situations. This labeling system was developed by National Fire Protection Association. Like HMIS, it includes labels and a numerical rating system, but the basic purpose of the label information is different.

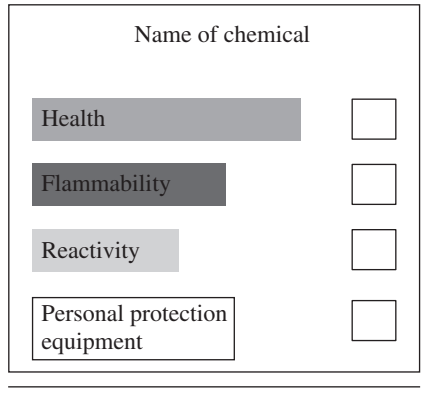
OSHA safety regulations do not require use of either the HMIS® or NFPA 704 systems; OSHA permits one to use any labeling system as long as it satisfies their requirements for "labels and other forms of warning" (29 CFR 1910.1200f).

Hazardous Materials Identification System (HMIS®)

HMIS® was developed by the National Paint and Coatings Association (NPCA) to help employers comply with OSHA's Hazard Communication Standard (HCS), 29 CFR 1910.1200.

The system utilizes colored bars, numbers, and symbols to convey the hazards of chemicals used in the workplace. The HMIS® labeling system satisfies a portion of the HCS requirements by allowing workers to identify, at a glance, the type and degree of hazards associated with each product they use. HMIS® labels can appear in a variety of formats. Some will include additional spaces to list target organ effects (a labeling requirement under 29 CFR 1910.1200) and other information, but the four colored areas will always be present. An example identification table is seen in Table 1.C.1.

TABLE 1.C.1 Example of Hazardous Materials Identification System.
(*See insert for color representation of the table*.)



Blue: Health

The Health section conveys the health hazards of the material. According to NPCA, the numeric hazard assessment procedure differs from that used by NFPA.

4. Life-threatening, major, or permanent damage may result from single or repeated overexposures (e.g., hydrogen cyanide).
3. Major injury likely unless prompt action is taken and medical treatment is given.
2. Temporary or minor injury may occur.
1. Irritation or minor reversible injury possible.
0. No significant risk to health.

Red: Flammability

In this category, the HMIS and NFPA systems are identical.

4. Flammable gases or very volatile flammable liquids with flash points below 73°F (23°C) and boiling points below 100°F (38°C). Materials may ignite spontaneously with air (e.g., propane).
3. Materials capable of ignition under almost all normal temperature conditions. Includes flammable liquids with flash points below 73°F (23°C) and boiling points above 100°F (38°C), as well as liquids with flash points between 73 and 100°F.
2. Materials which must be moderately heated or exposed to high ambient temperatures before ignition will occur. Includes liquids having a flash point at or above 100°F (38°C) but below 200°F (93°C) (e.g., diesel fuel).
1. Materials that must be preheated before ignition will occur. Includes liquids, solids, and semisolids having a flash point above 200°F (93°C) (e.g., canola oil).
0. Materials that will not burn (e.g., water).

ORANGE: PHYSICAL HAZARD

Reactivity hazard is assessed using the OSHA criterion of physical hazard. Seven such hazard classes are recognized: water reactives, organic peroxides, explosives, compressed gases, pyrophoric materials, oxidizers, and unstable reactives.

4. Materials that are readily capable of explosive water reaction, detonation or explosive decomposition, polymerization, or self-reaction at normal temperature and pressure.

3. Materials that may form explosive mixtures with water and are capable of detonation or explosive reaction in the presence of a strong initiating source. Materials may polymerize, decompose, self-react, or undergo other chemical change at normal temperature and pressure with moderate risk of explosion.

2. Materials that are unstable and may undergo violent chemical changes at normal temperature and pressure with low risk for explosion. Materials may react violently with water or form peroxides upon exposure to air.

1. Materials that are normally stable but can become unstable (self-react) at high temperatures and pressures. Materials may react nonviolently with water or undergo hazardous polymerization in the absence of inhibitors.

0. Materials that are normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react; nonexplosives.

WHITE: PERSONAL PROTECTION

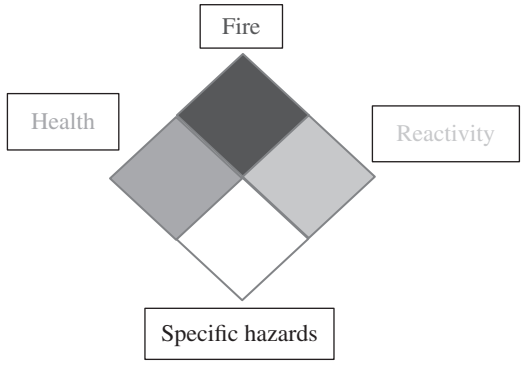
This is by far the largest area of difference between the NFPA and HMIS systems. In the NFPA system, the white area is used to convey special hazards, whereas HMIS uses the white section to indicate what personal protective equipment (PPE) should be used when working with the material.

NFPA 704 Hazard Identification Ratings System

The NFPA is an international nonprofit organization dedicated to reducing the burden of fire and other hazards on the quality of life by providing codes and standards, research, training, and education. NFPA membership totals more than 79,000 individuals from around the world and more than 80 national trade and professional organizations.

The familiar NFPA “hazard diamond” indicates health, flammability, and instability. The diamond is broken into four sections. Numbers in the three colored sections range from 0 (least severe hazard) to 4 (most severe hazard). The fourth (white) section is left blank and is used only to denote special fire-fighting measures/hazards. An example identification table is seen in Table 1.C.2.

TABLE 1.C.2 Example NFPA table. (*See insert for color representation of the table*.)



Blue: Health

1. Slightly hazardous (toxic) material which requires only minimal protection (e.g., safety glasses and gloves) in addition to normal work clothing to work with safely.

2. Moderately toxic or hazardous material which requires additional PPE or equipment (e.g., chemical goggles, lab/work smock, local ventilation) in addition to that required for less toxic material. Consult the SDS for specific health hazard and proper PPE to use with this material.

3. Highly to extremely toxic (deadly) material (and any carcinogen, mutagen, or
or teratogen). These materials will require specialized equipment (e.g., respirator or
4. exhaust hood, full-face shield, rubber apron, specialized gloves, handling tongs, etc.) beyond that required for moderately toxic material. You must consult the SDSs and/or other safety information to determine the hazard (acute or chronic)and the proper PPE and engineering controls for safely using this material.

Red: Flammability

In this category, the HMIS and NFPA systems are identical.

0. Materials that will not burn (e.g., water).

1. Materials that must be preheated before ignition will occur. Includes liquids, solids, and semisolids having a flash point above 200°F (93°C) (e.g., canola oil).

2. Materials which must be moderately heated or exposed to high ambient temperatures before ignition will occur. Includes liquids having a flash point at or above 100°F (38°C) but below 200°F (93°C) (e.g., diesel fuel).

3. Materials capable of ignition under almost all normal temperature conditions. Includes flammable liquids with flash points below 73°F (23°C) and boiling points above 100°F (38°C), as well as liquids with flash points between 73 and 100°F.

4. Flammable gases or very volatile flammable liquids with flash points below 73°F (23°C) and boiling points below 100°F (38°C). Materials may ignite spontaneously with air (e.g., propane).

ORANGE: REACTIVITY

1. A material that is normally stable but may be reactive if heated
2. A material capable of violent reaction
3. A material capable of shock or rapid heating
4. A material capable of detonation

WHITE: OTHER HAZARD INFORMATION

This information may include the following chemicals' or materials' properties:

- Radioactivity
- Proper fire extinguishing agent
- Skin hazard
- Its use in pressurized containers
- Protective equipment required (PPE)
- Unusual reactivity with water with the symbol "**W**"
- Words **ACID, COR** (corrosive), **RAD** (radiation), **OXY** (oxidizer), **Rad** (radioactive), **CARC** (carcinogen), or other abbreviations may also be used

HMIS® Versus NFPA: Determining which Labels to Use

- HMIS® is intended to be used by employers and workers on a daily basis and provides information on acute and chronic health hazards, flammability, physical hazards, and PPE.
- The system helps employers comply with OSHA's Haz Com standard.
- The emphasis of HMIS® on PPE and hazard communication makes it the better choice for keeping employees informed about everyday workplace hazards and how they can minimize exposure.
- NFPA's label information is intended for use by emergency response personnel (fire fighters, hazardous materials workers, police, etc.) under emergency conditions.
- Labels contain information on acute health hazards, flammability, physical hazards, and special characteristics that might require special fire-fighting techniques, such as reactivity with water.
- Facilities that store or use materials that require special handling under emergency situations may find the NFPA's system most useful. The additional information on special characteristics is particularly useful during a spill or fire.

FURTHER READING

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MORE RESOURCES

American Society for Healthcare Engineering (ASHE). An overview of National Fire Protection Association (NFPA) codes. NFPA establishes codes, standards, guidelines, and recommended practices for the prevention and control of fire.

American Society for Healthcare Engineering (ASHE). Discussion of the National Fire Protection Association's Life Safety Code® (NFPA 101) and other NFPA codes relevant to Healthcare.

Cole-Palmer Chemical Compatibility Information, http://www.coleparmer.com/techinfo/ChemComp.asp

Federal OSHA, http://partners.coleparmer.com/techinfo/chemcomp.asp

Glove selection chart at: http://www.bestglove.com

HMIS®—Hazardous Materials Identification System. A discussion presented by the Safety Emporium, a supplier of laboratory and safety supplies.

HMIS®—Hazardous Materials Identification System. New aerosol flammability rating criteria. The third version of this system, HMIS® III, offers comprehensive resources covering hazard assessment, hazard communication, and employee training. HMIS® III Hazard Assessment helps define the Health, Flammability and Physical Hazards of different chemicals, and shows how to communicate those hazards with a label that incorporates color-coded fields, along with a recommendation for personal protective equipment.

http://www.lpslabs.com/site_files/literature/HMIS3FlammabilityRatings_LPS.pdf

NFPA 704. A discussion presented by the Safety Emporium, a supplier of laboratory and safety supplies.

NFPA's Fire Protection Guide to Hazardous Materials, 13th edition includes NFPA 704, "Standard System for the Identification of the Hazards of Materials for Emergency Response" as well as pertinent information from a variety of other NFPA publications (including NFPA 704 ratings for over 3000 specific chemicals, information **not** included with NFPA 704).

On-line SDS Sites, http://www.msdssearch.com/DBLinksN.htm

OSHA Formaldehyde Standard Refer to Link, http://www.dir.ca.gov/title8/5217e.html

OSHA's Reporting Requirements for Regulated Carcinogens, Refer to Link, http://www.dir.ca.gov/title8/5209.html

The Latest National Toxicology Program List of Carcinogens at, http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html

HIPAA REFERENCE

http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule