

Safety Standards

Occupational Safety and Health Act, OSHA

Just as there are laws governing privacy, there are also regulations around safety and health standards. The federal Occupational Safety and Health Act, OSHA, was passed for the purpose of making the provision of a safe working environment a requirement for employers. Be aware that many states have adopted their own standards and enforcement policies that may go beyond OSHA standards. It is highly recommended that you visit the OSHA website so you may review applicable OSHA standards and to determine if your state has an OSHA Plan.

www.OSHA.gov

Further, there may be regional or local requirements. You will need to explore this as well to make sure you are in compliance.

Businesses are required to be OSHA compliant if they have one or more paid employees.

This includes:

- having safety programs in place
- posting both federal and, if needed, state OSHA posters (available through your state/federal OSHA office)
- providing safety training for employees

Employees must also comply with OSHA rules and regulations.

They are required to

- participate in their employer's safety program
- notify employers of any unnoticed hazards
- report any occupational illnesses or injuries

Employee Rights

Employees may not be terminated or maltreated due to reporting an illness or injury or for filing a complaint with OSHA as they have the right to ask for an inspection. Employees also have the right to receive a copy of their employer's written safety program and to review their own medical files.

Technically, OSHA requirements will not apply to volunteers. However, an organization does need to be concerned about the general well-being and safety of its volunteers. In addition to having a moral obligation to help make sure volunteers do not injure themselves, your organization may have potential liability exposure. As a good business practice and good faith effort, an organization should require that volunteers abide by its safety and training practices. Though adoption of OSHA standards may not be required for volunteers, from a risk management perspective, it is considered a best practice.

An example of a broad outline for an OSHA safety program and for an OSHA safety manual is below but please note, this OSHA information is meant only to serve as an overview and with the understanding that ECHO is not engaged in rendering legal or expert assistance. You will need to do your own research and develop your own program based upon federal, state, and local regulations. Utilizing resources that you have access to, such as a medical volunteer or a local OSHA expert may be able to provide you with a template that you can use to create your own program. If necessary, legal or professional assistance should be sought.

OSHA Safety Program EXAMPLE:

- Commitment of management by providing resources, support, and assignment of responsibilities
- A Safety Coordinator who conducts site specific hazard analysis and suggest and implements hazard controls.
 - This role may be assigned to a paid staff member or a volunteer and responsibilities should be documented in writing
- Development of a site specific OSHA Safety Manual (written program)
 - Consisting of related policies and procedures
- Employee training and education

OSHA Safety Manual EXAMPLE:

- Worksite Hazard Assessment Policy and Procedures
- Bloodborne Pathogen Program
- General Safety Program
- Emergency Action Plan
- Hazard Communication Program
- Ergonomics
- Workplace Violence
- Tuberculosis
- Employee Training
- Record Keeping

Clinical Laboratory Improvement Amendments (CLIA)

CLIA is a program established at the federal level to establish quality standards for all laboratory testing. The purpose is to ensure the accuracy, reliability, and timeliness of patient test results, regardless of where the test was performed. Under CLIA, a laboratory is defined as a facility that performs testing on material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of, human beings. What determines the level of CLIA license needed is based upon the complexity/type of testing that is being done.

Many clinics perform simple laboratory tests which require a CLIA Certificate of Waiver. This certificate is required regardless of how many test are performed and even if you do not charge the patient or file for third party reimbursement insurance. As determined by the FDA, waived test are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”

Example

- Finger sticks for blood glucose levels
- Urine dips

These both qualify as a waived laboratory test.

For a complete list of waived tests, go to the website:

www.cms.hhs.gov/clia

Some clinics may also perform tests that require a Provider Performed Microscopy Test (PPMP) certificate, such as when a provider uses a microscope during the course of a patient visit on specimens that may not be easily transportable.

Obtain a license to administer waived tests:

- Enroll in the CLIA program
- Pay certificate fee every two years (\$150.00)
- Follow the manufacturer's instructions for the waived tests you are performing

Obtain a license to administer PPMP tests:

- Enroll in CLIA program
- Pay certificate fee every two years (\$200.00)
- Perform certain quality and administrative procedures

To apply for CLIA Waiver/PPMP certificate(s):

- Fill out an application (Form CMS-116)
 - online at: www.cms.hhs.gov/clia
 - at their local state agency (list of state agencies is available on their website)

Regardless of what license you apply for, your clinic will also need to develop laboratory policies and procedures. As with other policies and procedures, if you can obtain an example from a healthcare volunteer, or even a local lab that will be supporting your functions, you can utilize this as a template and then make necessary changes to fit your needs.

Basic elements that you will need to incorporate:

- Lab safety procedures
- Staff and volunteer training
- Quality control and testing of equipment
- Sterilization/Cleaning Procedures

- Biohazard Waste Procedures
- Bloodborne Pathogen Exposure Procedures
- Specimen Collection Procedures