

Code: 4253

*Title: REGULATORY COMPLIANCE & LABORATORY SUPERVISOR-
HEALTH DEPARTMENT*

SUMMARY: Researches, coordinates and oversees the Pima County Health Department's compliance with relevant regulatory and statutory requirements, including but not limited to OSHA, HIPAA, CLIA and Pharmaceutical Security. Directs, plans, coordinates and oversees the PCHD medical laboratory activities, ensuring the accuracy and integrity of all tests, examinations and analyses performed in the department's clinical settings.

DUTIES/RESPONSIBILITIES: (Work assignments may vary depending on the department's needs and will be communicated to the applicant or incumbent by the supervisor.)

Maintains current knowledge of laws, rules and regulations and relevant legislation governing PCHD, including but not limited to OSHA, HIPAA, CLIA, Outpatient Clinics and Pharmaceutical operations, to ensure that the department's policies, procedures and activities comply with all regulatory requirements and standards;

Coordinates and participates in Department wide training in order to ensure all programs are in compliance with all regulatory requirements and standards including, but not limited to, OSHA, HIPAA, CLIA and relevant pharmacy dispensing laws;

Provides oversight and review to assure program compliance with regulatory requirements and standards (i.e., reviews each program's safety policies and procedures, compliance with departmental pharmacy inventory policies and procedures, etc.);

Performs as a department representative and subject matter expert to other sections of the department, other County departments, private sector and other agencies, entities and other jurisdictions at meetings, on committees, task forces, and boards at the local, and state level;

Reviews proposed legislation and rules and ensures the Department's and the public interests are taken into consideration in the legislative process;

Prepares comprehensive reports in order to satisfy reporting requirements of Federal, State and local regulatory agencies;

Initiates, develops and implements policies and procedures to assure optimal laboratory testing and analyses to obtain data for the use in diagnoses and treatment of disease;

Researches and selects testing methodology and establishes parameters for acceptable levels of analytic performance throughout the testing process including receipt, analyses and reporting;

Oversees and trains clinicians and staff performing waived laboratory testing at PCHD sites and obtaining specimens for hematological, chemical, serologic, urine, microbiological tests by establishing procedures for specimen handling, performance of the test, labeling, etc.;

Develops, implements and monitors the quality assurance and quality control program as required by certification agencies;

Develops, implements and evaluates laboratory in-service and new employee training;

Reviews tests performed by clinician staff to ensure quality and accuracy of tests and results;

Determines, and directs others in, actions to take to resolve testing, analyses and operational problems;

Interacts with medical staff for evaluation of diagnostic data;

Develops record keeping, reporting and communication protocols between different laboratory and clinic functions to assure timely and accurate data transmission and entry;

Evaluates employee performance, makes recommendations on hiring, terminations, and related personnel activities, and initiates progressive discipline process as necessary;

Identifies potential safety and health issues and develops strategies to effectively respond.

KNOWLEDGE & SKILLS:

Knowledge of:

- Clinical Laboratory Improvement Amendment (CLIA) laboratory regulations;
- Occupational Safety and Health Administration (OSHA) regulations;
- Health Insurance Portability and Accountability Act (HIPAA) standards, rules and regulations;
- Federal and State laws, rules and regulations governing the practice of pharmaceutical storage and dispensing;
- the principles and practices of medical laboratory technology and supervision.

Skill in:

- developing and implementing policies, procedures, quality control and quality assurance programs related to regulatory compliance;
- training staff in regulatory compliance;
- selecting, developing and testing test methodologies;
- assigning, training and supervising staff;
- using, calibrating and performing operator maintenance on laboratory instruments;
- handling potentially dangerous and infectious substances;
- establishing and maintaining effective working relationships with department staff and employees;
- overseeing and performing all medical laboratory tests, analyses and examinations;
- recognizing abnormal test results and instructing others in taking corrective actions;
- performing all medical laboratory tests, analyses and examinations;
- identifying bacteria and preparing specimens for testing;
- documenting information in and retrieving information from a computer database.

MINIMUM QUALIFICATIONS:

A Bachelor of Science degree from an accredited college or university with a major in medical technology, clinical laboratory science, chemical, physical, biological or related science and four year of medical laboratory experience including one year supervisory experience and three years experience overseeing regulatory compliance in a health care setting (which may be concurrent with the required medical laboratory experience).

OTHER REQUIREMENTS:

Licenses and Certificates: Certification as a Medical Technologist with the Registry of Medical Technologists of the American Society of Clinical Pathologists, or equivalent certification by a recognized health agency (e.g. HEW, AMT, NCA) is required at the time of appointment

Special Notice Items: Department of Labor regulations CFR Part 1910.1030 requires notification that this category may have a high risk of exposure to communicable diseases. Hepatitis B vaccine will be provided.

Physical/Sensory Requirements: Ability to distinguish color within normal range and to properly wear safety clothing and/or equipment. Other physical and sensory abilities will be determined by position.

This class specification is intended to indicate the basic nature of positions allocated to the class and examples of typical duties that may be assigned. It does not imply that all positions within the class perform all of the duties listed, nor does it necessarily list all possible duties that may be assigned.

Pima County

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