REGULATORY, LEGAL, POLICY COMPLIANCE

Purpose: The intent of the Department of Pathology is to comply with federal, state, and local requirements governing safety of the patient and employee, quality of testing and performance of processes and confidentially of information. Agencies, Institutions, Laws and Policies all contribute guidance to excellence in serving our customers. Only in adherence to such mandates can achievement of desired outcomes be met. It is in the quest of excellence that compliance with requirements and directives becomes imperative. It is with their agreement that we pledge adherence.

Principal Regulations:

Federal Regulations:

CLIA: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) is the primary federal legislation related to clinical laboratory quality and patient safety. All clinical labs in the United States must comply with the provisions of CLIA. CLIA is primarily administered by the Centers for Medicare and Medicaid Services(CMS), an agency of the United States Department of Health and Human Services (HHS). The Food and Drug Administration (FDA), another agency of HHS, administers the sections of CLIA that pertain to classification of tests. The Centers for Disease Control and Prevention (CDC) a third agency of HHS, maintains an active interest in CLIA.

Another important federal regulation that relates to the quality of laboratory operations is the Health Insurance Portability and Accountability Act of 1996. HIPAA contains standards governing the privacy and security of health information. HIPAA is administered by CMS and the Office of Civil Rights, both agencies of HHS.

A group of regulations administered by the FDA concerns medical devices (instruments, etc.) and biologics (blood and blood products). Regulations related to medical devices and biologics that are important to the clinical laboratory are the FDA’s Medical Device Amendment of 1976, Safe Medical Devices Act of 1990, and Good Manufacturing Practices (GMP) / Quality System (QS) Regulation of 1996.

State Regulations:

Most quality and patient safety requirements for clinical laboratories are federal. States issue requirements for notifiable infections diseases that must be reported by laboratories to local public health departments. Several states, Louisiana included, require licensure of medical technologists; licensure of technologists is not required by federal regulations.

Overview of Regulatory Requirements:

Types of Testing:

Every clinical laboratory test system sold by a manufacturer is classified into one of three groups: waived, moderate complexity, and high complexity. The FDA is responsible for classifying each laboratory test system, and the type of quality control activities that must be conducted varies for each class of tests. Tests classifications can be obtained from an FDA-approved test insert, the Federal Register or the FDA web site. Most systems are classified on basis of the complexity of the testing procedure, not the analyte being measured. Waived tests are not subject to CLIA quality standards because regulators consider these tests to be so easy to perform correctly that the chances of an error are negligible. Nonwaived tests (moderately and highly complex tests) are subject to CLIA quality standards. Moderately and highly complex tests have similar validation and quality control requirements in CLIA, but some requirements for highly complex tests are slightly more stringent.
Types of Laboratories

Waived laboratories are not subject to most regulatory requirements related to quality and patient safety. However, they must still meet the data privacy and security provisions of HIPAA and notify public health departments of reportable diseases, as required by state law.

Moderately and highly complex laboratories must satisfy the quality and patient safety provisions in CLIA. These labs must also meet HIPAA privacy and security requirements and report notifiable infectious diseases to state agencies.

Laboratory Registration:
All clinical laboratories in the United States must apply to the government. Waived laboratories obtain a certificate of waiver which exempts them from CLIA quality and safety standards, so long as these laboratories use only waived tests and follow manufacturers testing instructions. Laboratories performing moderate and high complexity testing receive a registration certification. The laboratory must indicate whether it will be inspected by CMS or an approved authority such as the CAP. LSUHSC-S Department of Pathology laboratories, including Point of Care Testing are inspected by the CAP.

Certification and Accreditation:
Registered laboratories that perform moderate and high complexity testing and which are subject to CLIA must progress to either certification of compliance or certification of accreditation. When an organization such as the CAP accredits a laboratory, CMS issues a “certificate of accreditation,” which substitutes for a certificate of compliance which is awarded when a laboratory is successfully inspected by CMS or its agent.

Other approved accrediting organizations in addition to the CAP are the American Association of Blood Banks, American Society of Histocompatibility and Immunogenetics, and the Joint Commission on Accreditation of Healthcare Organizations.

CAP Terms of Accreditation:
As a CAP accredited laboratory, LSUHSC-S is compliant with the CAP terms of accreditation and includes immediate notification of CAP regarding the following:
1. Investigation of the laboratory by a government entity or adverse media attention related to laboratory performance: notification must occur no later than 2 working days after the laboratory learns of an investigation or adverse media attention.
2. Change in laboratory test menu (notification must occur prior to starting new patient testing)
3. Change in location, ownership or directorship of the laboratory; notification must occur prior to the change(s); or in the case of unexpected changes, no later than 2 working days afterwards.

Applicable State and Local Laws and Regulations
Applicable state and local requirements may include but are not limited to the following areas: reporting of notifiable conditions (www.dhh.louisiana.gov morbidty report; LSUHSC-S Dept. of Infection control ), handling radioactive materials(NUHSC-S Safety Dept.), shipping infections or diagnostic materials (certified personnel, e.g. Microbiology and Reference Lab), personnel qualifications (LSUHSC-S Human Resources), retention of specimens and records (CLIA/CAP; Lab Policy and Information Manual), hazardous waste disposal (LSUHSC-S...
Policy 2.24
Page 3 of 3

Environmental Services and Safety departments), fire codes (LSUHSC-S Dept. of Safety) medical examiner or coroner jurisdiction (Anatomic Pathology), legal testing, handling controlled substances, patient consent for testing (Hospital Policy Manual), confidentiality of test results (Hospital Policy/Dept. of Information Management; Lab Policy and Information manual), and donation of blood (LSUHSC-S Transfusion Services). Information regarding applicability is readily available from hospital administration, hospital policies, hospital by-laws, hospital administrative directives, state departments of health, etc.

While the state of Louisiana permits DTC testing, direct to consumer testing is not practiced within the LSUHSC-S Dept. of Pathology. In-house test results are released electronically to pass word protected authorized recipients. Outside client test reports (Outreach ) may be faxed to a previously designated client location per contractual agreement. Genetic counseling is a function of Feist-Weiller CC. [www.feistweiller.org](http://www.feistweiller.org). Genetic testing results for predisposition conditions are provided to patients according to guidelines established by the Hereditary Cancer Risk Assessment Program at Feist-Weiller Cancer Center. Genetic testing results for perinatal patients are offered via Clinical Geneticists within the LSUHSC-S Perinatal Genetics services.

Exigency/Financial: Program modifications or discontinuances recommended by the institution (unit) and Chancellor and approved by the President must be approved by the Louisiana State University System Board of Supervisors. “As used herein, the term “unit” means any identifiable component of the LSU System at any level of its organization which has an annual budget for the operation of such component”. Discontinuance of services and associated retained materials are managed through oversight of the LSU System Board of Supervisors.

References:
CAP LAP checklist items, GEN 20374, GEN 26791, GEN 20425, GEN 41460.
Bylaws & Regulations, Board of Supervisors, Louisiana State University System, Section 5-13.