70243 Clinical Laboratory Service General Requirements

(a)

Clinical laboratories shall be operated in conformance with the California Business and Professions Code, Division 2, Chapter 3 (Sections 1200 to 1322, inclusive) and the California Administrative Code, Title 17, Chapter 2, Subchapter 1, Group 2 (Sections 1030 to 1057, inclusive).

(b)

All hospitals shall maintain clinical laboratory services and equipment for routine laboratory work, such as urinalysis, complete blood counts, blood typing, cross matching and such other tests as are required by these regulations.

(c)

All hospitals shall maintain or make provision for clinical laboratory services for performance of tests in chemistry, microbiology, serology, hematology, pathology and such other tests as are required by these regulations.

(d)

Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

(e)

The responsibility and the accountability of the clinical laboratory service to the medical staff and administration shall be defined.

(f)

The director of the clinical laboratory shall assure that: (1) Examinations are performed accurately and in a timely fashion. (2) Procedures are established governing the provision of laboratory services for outpatients. (3) Laboratory systems identify the patient, test requested, date and time the specimen was obtained, the time the request reached the laboratory, the time the laboratory completed the test and any special handling which was required. (4) Procedures are established to ensure the satisfactory collection of specimens. (5) A communications system to provide efficient information exchange between the laboratory and related areas of the hospital is established. (6) A quality control system within the laboratory designed to ensure medical reliability of laboratory data is established. The results of control tests shall be readily available in the hospital. (7) Reports of all laboratory examinations are made a part of the patient's medical record as soon as is practical. (8) No laboratory procedures are performed except on the order of a person lawfully authorized to give such an order.

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(g)

Tissue specimens shall be examined by a physician who is certified or eligible for certification in anatomical and/or clinical pathology by the American Board of Pathology or possesses qualifications which are equivalent to those required for certification. Oral specimens may be examined by a dentist who is certified or eligible for certification as an oral pathologist by the American Board of Oral Pathology. A record of his findings shall become a part of the patient's medical record. (1) A tissue file shall be maintained at the hospital or the principal office of the consulting pathologist.

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(h)

The use, storage and disposal of radioactive materials shall comply with the California Radiation Control Regulations, Subchapter 4, Chapter 5, Title 17, California Administrative Code.

(i)

Where the hospital depends on outside blood banks, there shall be a written agreement governing the procurement, transfer and availability of blood.

(j)

Periodically, an appropriate committee of the medical staff shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration.