

LAWS AND REGULATIONS

RELATING TO

COUNTY AND MUNICIPAL LABORATORIES

Excerpts from the

CALIFORNIA HEALTH AND SAFETY CODE

AND THE

CALIFORNIA CODE OF REGULATIONS

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LABORATORY FIELD SERVICES
STATE OF CALIFORNIA DEPARTMENT OF HEALTH SERVICES
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LAWS RELATED TO PUBLIC HEALTH LABORATORIES
CALIFORNIA HEALTH AND SAFETY CODE Division 101, Part 3,
Chapter 2, Article 5 Sections 101150 – 101165
ARTICLE 5 MUNICIPAL AND COUNTY LABORATORIES

101150. For the purpose of protecting the community and the public health, the local health department of a city or county shall have available the services of a public health laboratory for the examination of specimens from suspected cases of infectious and environmental diseases, that may include, but need not be limited to, the examination of specimens from milk, milk products, waters, food products, vectors, and the environment. The public health laboratory shall also provide the analyses required to assist in community disease surveillance and to meet the responsibilities and support the programs of the local health department.

101155. The cost of establishment and maintenance of the public health laboratory is a legal expenditure from any city or county funds that are for disbursement under the direction of the city or county health officer to protect public health.

101160. (a) Any city or county public health laboratory established for the purposes set forth in this chapter and its personnel shall be approved by the State Department of Health Services and shall comply with the requirements of CLIA.

(b) For purposes of this section, "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100—578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208 of the Business and Professions Code.

101165. Nothing in this article, or any other provision of law, shall be construed to restrict, limit, or prevent individuals certified under authority of this part or Article 1 (commencing with Section 106600) of Chapter 4 of Part 1 of Division 104 from performing their duties for the protection of the public health.

**REGULATIONS RELATING TO PUBLIC HEALTH LABORATORIES
CALIFORNIA CODE OF REGULATIONS (Title 17, Subchapter 1, Group 3)
Group 3. County and Municipal Laboratories**

Article 1. Official Public Health Laboratory Service Required

1075. Local Health Departments. Each local health department shall have available the services of an official public health laboratory. The laboratory of the State Department of Health is hereby designated as the official laboratory for all local health department jurisdictions not covered by local laboratory service.

1076. Certificates of Approval Required. A certificate of approval issued after inspection by the Department shall be required to be in the possession of and be on display in every principal and branch public health laboratory and no such laboratory shall continue to operate following receipt of notice of cancellation of any existing certificate, or of refusal of the Department to issue a certificate.

1076.1 Public Health Laboratory. The official public health laboratory shall consist of a principal public health laboratory and may include branch public health laboratories.

- (a) The principle public health laboratory is the laboratory facility that provides the major or total laboratory services to a public health department.
- (b) A branch public health laboratory is any laboratory facility that provides minor or auxiliary laboratory services.

1077. Reports Required. The following reports shall be transmitted to the Department by all laboratories approved under Section 1076. Standard forms shall be used if provided by the Department.

- (a) A report shall be made semiannually during the months of January and July, of work load data and personnel information as requested by the Department.

- (b) A report shall be given within 30 days:
 - (1) Of any change in the directorship of the laboratory.
 - (2) Of any proposed expansion, reduction or shift in the laboratory services.
 - (3) Of any change in the location of the laboratory.

- (c) Such additional reports shall be made as required by the Department.

1078. Minimum Requirements Specified. Any laboratory approved under Section 1076 shall meet the following minimum requirements:

- (a) Maintain adequate equipment and facilities and sufficient personnel to carry on dependable public health laboratory work.
- (b) Employ procedures, technics, and reporting practices approved by the Department.
- (c) Establish and maintain for a minimum of two years adequate record systems and files of laboratory work done.
- (d) Conduct, maintain, and operate programs, acceptable to the Department; for controlling the quality of test performance.
- (e) Demonstrate satisfactory performance in a proficiency-testing program approved by the Department.
- (f) Maintain and conduct the laboratory in a manner approved by the Department.
- (g) Employ personnel as provided in this article.
- (h) Accept specimens for examination as an aid to patient management only from, and issue reports only to, persons licensed under the provisions of the law relating to the healing arts or their representatives.
- (i) Employ procedures and precautions to provide for the safety and health protection of all persons in the laboratory.

1079. Professional Personnel to be certified.

- (a) No person may act as a Public Health Microbiologist in any laboratory certified under Section 1076 who is not in possession of a Public Health Microbiologist's Certificate issued by the Department.
- (b) The Department may issue temporary certificates to applicants who meet the requirements for admission to the next scheduled examination when this is deemed to be reasonably necessary for the provision of public health laboratory services. Temporary certificates may not be issued to applicants who have failed to pass certification examinations.
- (c) Examinations, either written or oral, or both, for the certificate of Public Health Microbiologist shall be held as needed and where designated by the Department. Such examinations shall be under the supervision of the Department.
- (d) The minimum requirements for admission to the examinations for a certificate as Public Health Microbiologists shall be as follows:
 - (1) Holds an earned doctoral degree from an accredited institution with a chemical, physical or biological science as a major, and has completed at least one year of post doctoral laboratory training in medical and public health microbiology approved by the Department; or
 - (2) A baccalaureate or higher degree with a major in Medical or Public Health Microbiology, or equivalent major as determined by the Department, with courses acceptable to the Department, from a college or university accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency, as determined by the Department; and experience represented by at least six months as a

Public Health Microbiologist-trainee in a public health laboratory approved by the Department for such training; or experience equivalent to this training as determined by the Department in a laboratory acceptable to the Department.

- (e) No person shall perform any test or make any examination in any laboratory certified under Section 1076 unless he is in possession of a valid Public Health Microbiologist's certificate or is otherwise approved by the Department to perform specified laboratory procedures.
- (f) Every person certified as a Public Health Microbiologist shall report to the Department within 30 days any change of name or mailing address giving both the old and new names and addresses.
- (g) Certificates may be denied, revoked or suspended for any of the following reasons:
 - (1) Conviction of a felony or of any misdemeanor involving moral turpitude, under laws of any State or of the United States, arising out of or in connection with public health laboratory practice. The record of conviction or a certified copy thereof shall be conclusive evidence of such conviction.
 - (2) Violation of any provision of the Business and Professions Code governing the practice of medicine and surgery.
 - (3) Violation of these regulations.
 - (4) Knowingly making a false statement concerning a material matter on an application for certification, or on an application for approval as a trainee.

- (5) The use of any degree, certificate or title in any manner, which has been purchased or procured by barter or any unlawful means or obtained from any institution which at the time said degree, certificate or title was obtained was not recognized or accredited by the proper authorities of the state where said institution was located to give training in the field of study in which the degree, certificate or title is claimed.
- (6) The use of drugs or alcoholic beverages to the extent, or in such a manner, that such use impairs the ability of the certified person to practice his profession with safety to other persons in the laboratory or to the public.
- (h) Proceedings under paragraph (g) above shall be conducted in accordance with Chapter 5, Part I, Division 3 of Title 2 of the Government Code.

1080. Professional Training.

- (a) For purposes of this section a person receiving professional training required for certification as a Public Health Microbiologist shall be designated as a Public Health Microbiologist-trainee.
- (b) The credentials of a Public Health Microbiologist-trainee shall be approved by the Department prior to appointment.
- (c) The appointment or separation of a Public Health Microbiologist-trainee shall be reported within 5 days to the Department giving the date of appointment or separation.
- (d) Laboratories which accept personnel for training as Public Health Microbiologist-trainees shall be specifically approved for such training by the Department. The minimum requirements for approval as training laboratories shall be established by the Department.

- (e) A Public Health Microbiologist-trainee shall not be entrusted with any microbiological examination except under the supervision of qualified personnel, nor shall he issue or sign a laboratory report for any test which he is scheduled for training for certification as a Public Health Microbiologist.

1081. Certain Cultures and Specimens to be sent to the State Laboratory.

- (a) All laboratories making examinations for identification of typhoid carriers shall, in all positive cases, forward to the Department a culture of the organism, the isolation of which established the diagnosis.
- (b) Whenever a laboratory receives a specimen for the laboratory diagnosis of suspected human cases of plague or botulism such laboratory shall communicate immediately by telephone or telegraph with the Department for instructions.
- (c) Any other specimens or cultures shall be submitted as required by the communicable disease regulations, Sections 2500 to 2699.

1082. Certain Specimens to be Sent to Approved Laboratories. Whenever specimens are taken for laboratory diagnosis of rabies or botulism, or for release from isolation of cases of diphtheria, typhoid fever, salmonellosis, or shigellosis, they shall be sent by the physician to a Public Health Laboratory approved for such work by the Department in accordance with Section 1076.

1083. Inspection to be made. Laboratories approved under Section 1076 shall be inspected by a duly authorized representative of the Department, for maintenance and conduct in conformity with these regulations. When deemed advisable, the Department may send check specimens to local laboratories to evaluate the accuracy and precision

of specific test performance.

1084. Health Departments may Contract with Private Laboratories. A health officer of a municipality or county may designate any laboratory as an official public health laboratory to perform any of the basic services, as defined under Section 1276(f). Any such laboratory shall be subject to the same requirements as an official public health laboratory as heretofore provided under Sections 1075 to 1083, inclusive.

REGULATIONS RELATING TO PUBLIC HEALTH LABORATORIES CALIFORNIA

CODE OF REGULATIONS (Title 17, Chapter 3, Subchapter 1)

Chapter 3. Local Health Service

Subchapter 1. Standards for State Aid for Local Health Administration

Article 1. Organization

1255. Public Health Laboratory. The principal public health laboratory shall be under the direction of a public health laboratory director. A branch public health laboratory shall be under the direction of a branch public health laboratory director who shall be directly responsible to the director of the principal public health laboratory.

Article 2. Program

1276. Basic Services. The health department shall offer at least the following basic services to the health jurisdiction which it serves:...

- (f) Laboratory services, provided by an approved public health laboratory in health departments serving a population of 50,000 or more. Such laboratories shall provide:
 - (1) Services necessary for the various programs of the health department.

- (2) Consultation and reference services to further the development of improved procedures and practices in laboratories employing such procedures related to the prevention and control of human disease.

Article 3. Personnel

1302. Director of the Public Health Laboratory. The director of a principal public health Laboratory shall be a certified Public Health Microbiologist whose qualifications conform with the specifications for this position as established by the Department, pursuant to the provisions of the Health and Safety Code. He shall have had four or more years of experience in public health laboratory work. The quality, variety and currency of this experience shall be satisfactory to the Department.

1302.1. Director of a Branch Public Health Laboratory. The director of a branch public health laboratory shall be a certified Public Health Microbiologist whose qualifications conform with the specifications for this position as established by the Department, pursuant to the provisions of the Health and Safety Code. He shall have had two or more years experience in public health laboratory work. The quality, variety and currency of this experience shall be satisfactory to the Department.

