

19a-36-A25. Laboratories to register**Laboratories to Register****19a-36-A25. Laboratories to register**

Any person, firm or corporation, or the duly authorized agent thereof, operating or maintaining a laboratory in which there is made any examination, determination or test specified in section 19a-36-A26, shall register such laboratory with the state department of health before any such examination, determination or test is made. The carrying on of any of the examinations, determinations or tests specified in said section shall be deemed the operating or maintaining of a laboratory.

(Effective October 25, 1989.)

19a-36-A26. Registration required when. Exemptions

- (a) Except for laboratory work of the types hereinafter exempted, registration is required for any of the following laboratory procedures:
- (1) Those which utilize any living agent capable of causing human infections or reportable disease of man, or which are used to secure evidence bearing upon the presence or absence of such living agents or the illnesses caused;
 - (2) those used to determine the sanitary quality of water or the amount of pollution therein or to control and evaluate the effectiveness of water treatment
 - (3) those performed on sewage, sewage effluent or sewage sludge in connection with investigation of sources of pollution, problems of sewage disposal or effectiveness of sewage treatment;
 - (4) any examination, determination or test performed on any sample of milk, cream, frozen dessert, milk product or milk beverage or of any container or package used or intended to be used for holding any such product;
 - (5) those used to determine the sanitary quality of any substance used as a food, or as an ingredient of food or as a container for food, or to determine whether or not such substance may be harmful to health;
 - (6) those performed on any material or substance for the purpose of determining the effectiveness of sanitation in the establishment serving food or beverages to the public;
 - (7) those performed on air or materials contributing substances to the air which may be prejudicial to health, except those performed for routine operational control or maintenance purposes.
- (b) Laboratories performing any of the work specified above shall be exempt from the requirements of this section only when all such work is done under one or more of the following conditions:
- (1) When laboratory findings are obtained in a laboratory facility and service maintained by a licensed practitioner of a healing art exclusively for the examination of his own patients within the scope of his license to practice;
 - (2) when the laboratory has been established as an agency of the state or federal government for the purpose of providing data for state or federal officials in the enforcement of the dairy and pure food and drug laws;
 - (3) when laboratory work is confined to butter fat tests on milk and cream for use in determining payment to producers of such products under provisions of the general statutes;
 - (4) repealed, March 23, 1976;
 - (5) when laboratory findings are obtained on materials derived from animals in a laboratory facility and service maintained by a Veterinarian licensed to practice in Connecticut performing laboratory examinations exclusively on animals under his or her care and treatment.
- (c) When the laboratory work consists solely of those tests necessary to control the operation of water treatment plants under the supervision of operators whose qualifications have been approved by the state department of health or of sewage treatment plants under the supervision of operators whose qualifications have been

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approved by the state department of environmental protection, upon recommendation of the division of environmental health services in the former case or the state department of environmental protection in the latter case, the department shall grant registration without approval as provided in section 19a-36-A33 solely for the purpose of allowing such operators to perform those tests as shall be required for the control of treatment. Such granting of limited registration or renewal thereof may be made by the department without prior inspection or investigation of facilities, personnel, equipment and proficiency.

(Effective October 25, 1989.)

19a-36-A27. Application for registration or reregistration

(a) Application for registration shall be made on forms provided for the purpose by the state department of health and shall set forth clearly essential information concerning the laboratory, including its name, its location, the name of the person, firm or corporation owning or operating it, and such additional information as the state department of health may at any time deem necessary regarding the tests to be made, the housing, equipment and personnel of the laboratory. As part of the application for registration, the owner of the laboratory, or his duly authorized agent, shall designate a person to be in charge of the laboratory and shall agree to notify the state department of health in writing before any change in status of the person in charge or removal of the laboratory to new quarters is made.

(a) In a similar manner, application for reregistration of such laboratory shall be made

- (1) biennially within thirty calendar days prior to expiration of the registration then current,
- (2) before the laboratory is moved to new quarters,
- (3) whenever a change in status of the person designated to be in charge is about to be made or
- (4) whenever registration has lapsed for any cause.

(Effective October 25, 1989.)

19a-36-A28. Conditional permission to operate laboratory

The state department of health may extend conditional permission to operate an unregistered laboratory for a period not to exceed thirty days pending completion of investigation or carrying out of conditions imposed prior to registration or reregistration.

(Effective October 25, 1989.)

19a-36-A29. Granting of registration

Registration or reregistration of a laboratory will be granted only after the state department of health has determined by inspection and investigation that no condition or circumstance exists which would, in the opinion of the state department of health, cause the laboratory to be operated in a manner prejudicial to the health of the public.

(Effective October 25, 1989.)

19a-36-A30. Suspension or revocation of registration

Registration of a laboratory may be suspended at any time when investigation has shown that the registration agreement has been violated or that the laboratory is being operated in a manner which may be prejudicial to the health of the public. Registration may be revoked for such cause after notice to and hearing of the parties interested.

(Effective October 25, 1989.)

19a-36-A31. Inspections and investigation by state department of health

Representatives of the state department of health shall be granted reasonable access to laboratory quarters and records for inspection and investigation. Whenever necessary to evaluate the accuracy of any type of laboratory work done in a laboratory which is registered or has

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19a-36-A32. Prohibition of transmission of material to unregistered laboratory

applied for registration, said department will require technical reviews of procedures used or submit a reasonable number of suitable specimens or samples and require reports thereon.
(Effective October 25, 1989.)

19a-36-A32. Prohibition of transmission of material to unregistered laboratory

No person, firm or corporation shall, without approval in writing from the state department of health, maintain, conduct or operate a station or office for the reception from the public of materials to be transmitted to a laboratory for the making of any clinical, medical, or sanitary laboratory examination, determination or test except when the laboratory in which the work is to be done is currently registered with the state department of health or is exempt from registration requirements, as provided for in section 19a-36-A26.
(Effective October 25, 1989.)

19a-36-A33. Requirements and standards for approval

- (a) The state department of health will approve registered laboratories only under the following circumstances:
- (1) When such approval is sought in order to comply with provisions of the general statutes or the public health code of Connecticut making approval a prerequisite for the performance of laboratory tests for the purposes specified therein;
 - (2) when laboratory tests for the diagnosis of reportable diseases of man are to be made in a laboratory serving a hospital, or
 - (3) whenever the state department of health deems that the application of standards for approval of a laboratory would be in the interests of the public health. When any of the foregoing conditions exist, the person in whose name a laboratory is registered may apply to the state department of health for approval of such laboratory to perform one or more examinations, determinations or tests specified in section 19a-36-A26. If after inspection and investigation such laboratory is found to conform to the requirements and standards for approval that are required by said department, the laboratory may be designated as an approved laboratory to perform examinations, determinations or tests specified. In recognition thereof the department shall issue a certificate of approval in the name of the individual who is designated by the owner of the laboratory, or by his authorized agent, to be the individual in charge of the work for which approval is requested.
- (b) Requirements and standards for approval of laboratories shall be based upon the ability and qualifications, as determined by investigation or examination, of the individual designated by the owner to be in charge of the laboratory and to the extent deemed necessary at any time of persons performing the examinations, determinations or tests; upon the standards and agreements set forth in section 19-4-1; and upon agreement on the part of the individual in charge to adhere to the standards upon which approval is based for making the specified examinations, determinations or tests. Approval shall lapse at any time that registration has expired or approval may be revoked or suspended at the discretion of the state department of health if at any time the standards of performance is found to be below that required. Certificates of approval shall expire at the end of each registration period and shall be returned at any time if revoked or suspended.
(Effective October 25, 1989.)

19a-36-A35. Standard tests for syphilis

A standard laboratory blood test or a standard serological test for syphilis as required under the provisions of the general statutes or the public acts shall be a serological test approved by, and performed in a manner that meets the approval of the state department of health. The following types of tests are so approved: VDRL slide flocculation, fluorescent treponemal antibody absorption (FTA-ABS), automated reagin (ART) and rapid plasma reagin (RPR) circle card tests.

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(Effective October 25, 1989.)