CHAPTER 5. CLINICAL LABORATORIES

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Authority

The provisions of this Chapter 5 issued under section 2102 of The Administrative Code of 1929 (71 P. S. § 532); and The Clinical Laboratory Act (35 P. S. §§ 2151—2165), unless otherwise noted.

Source

The provisions of this Chapter 5 adopted May 25, 1962, amended June 14, 1974, effective June 15, 1974, 4 Pa.B. 1220, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 211.14 (relating to diagnostic services); 28 Pa. Code § 501.4 (relating to regulations); 28 Pa. Code § 501.75 (relating to laboratory services); 28 Pa. Code § 565.2 (relating to laboratory service policy); and 28 Pa. Code § 715.14 (relating to urine testing).

GENERAL PROVISIONS

§ 5.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Clinical Laboratory Act (35 P. S. §§ 2151—2165).

Advisory committee—A group of persons as designated by the act who are experienced in the clinical laboratory field and appointed by the Secretary for the purpose of advising the Secretary in matters relating to the administration of the act. At least one member shall be qualified in the discipline of anatomic pathology and one in clinical pathology and licensed to practice medicine in this Commonwealth or eligible for licensure, one shall be qualified in the field of clinical chemistry, and one shall be qualified in the field of clinical microbiology.

Clinical Laboratories Improvement Act of 1967 (CLIA)—Section 353 of the act of July 1, 1944, Pub. L. No. 90-174 (42 U.S.C.A. § 263), and the regulations which apply thereto.

Clinical laboratory—Clinical laboratory includes the following:

(i) A place, establishment or institution organized and operated primarily for the performance of bacteriological, biochemical, microscopical, serological or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health. The term includes, but is not limited to, independent, hospital, industrial, state, county and municipal laboratories and clinical laboratories operated in private offices and clinics of practitioners of the healing arts.

(ii) The term does not apply to the office or clinic of a licensed practitioner of the healing arts who performs only the following procedures as part of his or her examinations of the patient to obtain results which are essential for the immediate diagnosis and therapy of the patient:

(A) Chemical examinations of urine by ''Dipstik'' or tablet methods or both.

(B) Microscopic examination of urine sediment.

(C) Pregnancy tests.

(D) Red and white blood cell counts.

(E) Sedimentation rate of blood.

(F) Gram stain.

(G) Primary culturing for transmittal to a licensed laboratory including pre-incubation, if required.

(H) Qualitative chemical examination of stool specimens.

(I) Test for pinworms.

(J) Test for Trichomonas vaginalis.

(iii) The list set forth in subparagraph (ii) may be revised by the Department in the event it is deemed advisable to add or eliminate specific procedures which either qualify or which no longer qualify as exempt items under the meaning and intent of this section.

(iv) Such procedures may be performed by the practitioners personally or with the aid of an assistant who need not be otherwise qualified.

(v) In the circumstances described in subparagraph (ii), the practitioner shall not be required to obtain a permit before carrying out such laboratory work.

Department—The Department of Health of the Commonwealth.

Director—The person designated by the registrant to be responsible for the daily technical and scientific operations of the laboratory including choice and application of methods, supervision of personnel and reporting of findings.

Owner—Any individual, partnership, group, firm or corporation holding or claiming ownership of or title to a laboratory.

Permit—A license issued by the Department which allows the operation of a clinical laboratory under the provisions of the act.

Secretary—The Secretary of Health of the Commonwealth.

Specimen—Only materials derived from the human body regardless of the physical character of such material.

Supervisor—A properly qualified individual, who, under the direction of an authorized director, may supervise the general activities of a clinical laboratory, or a properly qualified individual who under the direction of an authorized director, may supervise the technical work in a laboratory category.

Technologist—A properly qualified individual according to the provisions set forth in § 5.24 (relating to qualifications of technical personnel).

Source

The provisions of this § 5.1 amended through February 26, 1976, 6 Pa.B. 392. Immediately preceding text appears at serial pages (23192) and (23193).

§ 5.2. Scope and exception.

This chapter is applicable to all clinical laboratories operating within this Commonwealth except those specifically excluded under section 13 of the act (35 P. S. § 2163). A licensed laboratory approved to perform tests for syphilis under the

act is also an approved laboratory to perform these tests under sections 12 and 13 of the Disease Prevention and Control Act of 1955 (35 P. S. §§ 521.12 and 521.13).

Source

The provisions of this § 5.2 amended July 6, 1979, effective July 7, 1979, 9 Pa.B. 2250. Immediately preceding text appears at serial page (37439).

PERMITS

§ 5.11. Permit, requirements, application and conditions.

(a) No person, organization or establishment may operate a clinical laboratory in this Commonwealth without first obtaining a permit from the Department.

(b) Application for a permit to operate a clinical laboratory shall be made by the director thereof on forms provided by the Department. The application shall be accompanied by a filing fee of $25 payable to the Department; the fee will be retained by the Department.

(c) The application shall include the following information:

(1) The name and address of the owner or his authorized agent and information regarding the owner as may be required.

(2) The name and address of the clinical laboratory director and other technical personnel to be employed.

(3) Name and address of the clinical laboratory for which the permit is requested and a description and plan of the premises to be occupied for the operation of the laboratory.

(4) A list of the major laboratory equipment to be utilized, including the manufacturer's name and model number, and other pertinent specifications as may be required on the application form.

(5) The tests to be performed in the clinical laboratory.

(6) The internal and external quality control systems to be employed in the clinical laboratory.

(7) Answers to other questions required in the completion of the application form provided by the Department.

(d) A clinical laboratory director may obtain a permit for all or any designated part of one or more of the following categories:

(1) Microbiology, including the subcategories of bacteriology, virology, mycology, parasitology, syphilis serology and nonsyphilis serology.

(2) Hematology, including immunohematology.

(3) Clinical chemistry, including urinalysis.

(4) Tissue pathology, including exfoliative cytology.

(5) Radioisotope technics.

(e) A category, or subcategory (part), may be retained in a clinical laboratory permit as long as there is evidence that the laboratory functions actively in that category or subcategory and performs a reasonable number of tests to maintain its proficiency, as determined by the Department. Addition of a new category or

subcategory may require a period of proficiency evaluation not to exceed 6 months before approval is granted.

(f) No clinical laboratory or other establishment may collect or receive specimens from patients in this Commonwealth for testing unless the laboratory possesses a valid permit issued under this chapter or holds an appropriate Federal license if the laboratory is located outside of this Commonwealth.

(g) A licensed clinical laboratory may send specimens or portions of specimens which it receives to a consulting or reference laboratory approved by the Department. However, the sending clinical laboratory may not serve primarily as a receiving or relay station. A collecting, receiving or relay station may not be maintained by a laboratory or agent of a laboratory which does not hold a currently valid permit to operate a clinical laboratory in this Commonwealth.

(h) In order for a permit to become and remain valid, an annual registration fee shall be paid in full to the Department on or before November 15, 1983, and August 15 of each year thereafter upon receipt of billing forms from the Department. The amount of the fee shall be $100 for each category for which approval is granted. The maximum fee required for each laboratory will not exceed $500 per annum.

Source

The provisions of this § 5.11 amended through October 21, 1983, effective October 22, 1983, 13 Pa.B. 3218. Immediately preceding text appears at serial pages (43941), (66805), and (66806).

Cross References

This section cited in 58 Pa. Code § 21.8 (relating to boxers).

PERSONNEL

§ 5.21. Qualifications of director.

(a) No person shall be a director of a clinical laboratory unless he conforms with one of the following requirements:

(1) He shall hold a doctor of science degree or its equivalent in the basic sciences of chemistry, biology or microbiology or a doctoral degree in public health, medicine, osteopathy, pharmacy, dentistry or veterinary medicine from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education of the Commonwealth of Pennsylvania, and who has had 2 years' experience in a laboratory acceptable to the Department or is certified by the American Board of Pathology, American Osteopathic Board of Pathology, American Board of Microbiology, American Board of Bioanalysis. American Board of Clinical Chemistry, or other national accrediting board in laboratory specialties acceptable to the Department.

(2) He shall hold a master of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of

Regional Accrediting Agencies or the Department of Education of the Commonwealth, in chemistry, biology or microbiology, and who has had a minimum of 4 years' experience in a laboratory acceptable to the Department.

(3) He shall hold a bachelor of science degree or its equivalent in the basic sciences from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education, in chemistry, biology or microbiology, and who has had a minimum of 5 years experience in laboratory work in a laboratory acceptable to the Department.

(b) In addition, he may be required to pass a written, oral or practical qualifying examination in general laboratory science in one or more of the laboratory categories.

(c) On and after July 1, 1973, the proposed director of a clinical laboratory applying for a permit shall meet the requirements in subsection (a)(1) or (2).

(d) On and after July 1, 1974, the proposed director of a clinical laboratory applying for a permit shall meet the requirements in subsection (a)(1).

(e) The limitations of subsections (c) and (d) will not apply to those persons operating a clinical laboratory prior to February 6, 1973.

§ 5.22. Responsibilities of owner and director.

(a) The owner and director, jointly and severally, shall be responsible for the proper maintenance and ethical operation of the clinical laboratory and for any violations of these and other existing provisions. The Department will be notified in writing within a 30-day period of changes in the directors or general supervisor, and of all other technical personnel changes on a 6-month basis. Significant changes in physical facilities shall be reported to the Department within 30 days after initiation of the changes.

(b) The owner shall be responsible that the clinical laboratory is at all times under the direction of a director acceptable to the Department as set forth in this section. Whenever the designated director is to be on leave from his duties for more than 30-calendar days, the registrant shall so notify the Department in advance and shall designate, subject to approval of the Department, an interim director of the laboratory.

(c) The owner shall notify the Department in advance whenever the designated director is expected to terminate his services with the laboratory. Permission may be granted to continue operation of a clinical laboratory for not more than 6-calendar weeks under a general supervisor who does not meet the qualifications of a director. In extenuating circumstances, permission to operate longer without a permanent director may be granted subject to conditions specified in writing by the Department.

(d) The owner and director shall, if different persons, be jointly and severally responsible for the operation of the clinical laboratory in compliance with this section and with other pertinent regulatory and statutory requirements. They shall be responsible for the employment of personnel meeting qualifications specified

in this chapter. They shall submit to the Department, on forms provided by the Department, an annual report of the number and types of laboratory examinations performed during the preceding year.

(e) The director shall be responsible for the proper performance of all tests in the laboratory. He shall direct and supervise such tests and be responsible for the work of subordinates. He shall be responsible for the continuous application of quality control procedures to the work in accordance with recommendations and directives of the Department. Laboratory records of all work performed shall indicate the name of the director, and be signed by or otherwise indicate the person who actually performed the test.

(f) No person may act as a director of more than two clinical laboratories.

(g) A director shall be present for a reasonable period of each working day in each laboratory for which he is director.

§ 5.23. Qualifications of a supervisor.

(a) No person shall be a supervisor in a clinical laboratory unless he conforms with one of the following requirements:

(1) He shall have an earned doctoral degree from an accredited institution and shall have gained at least 2 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.

(2) He shall hold a M.A. or M.S. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 4 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.

(3) He shall hold a B.S. or A.B. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 6 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.

(b) The following two categories of supervisors shall be recognized:

(1) A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed. The director may also qualify as a general supervisor.

(2) A technical supervisor who meets the requirements of subsection (a)(1), (2) or (3) and provides direct supervision for the technical performance of the staff in one or more of the major categories, that is, microbiology, hematology and immunohematology, clinical chemistry and radioisotope technics during the periods in which tests are performed.

(c) Notwithstanding other provisions of this chapter, an individual who has been employed in a clinical laboratory as a supervisor prior to the effective date

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of this chapter may continue to act in that capacity after the date and may not be required to meet the requirements in subsection (a).

§ 5.24. Qualifications of technical personnel.

(a) A clinical laboratory technologist shall perform clinical laboratory tests with minimal supervision by the director or supervisors, while working in those areas in which he is qualified by education or experience. A clinical laboratory technologist shall have the following qualifications:

(1) A baccalaureate degree in medical technology or in a chemical, physical or biological science and clinical education in a program accredited by an agency recognized by the Department which includes 1 year of experience acceptable to the Department.

(2) An individual without the baccalaureate degree may become qualified as a technologist according to the provisions of section 241 of Title XI of the Social Security Amendments of 1972 Public Law 92-603 (42 U.S.C.A. § 1320a-2).

(b) Technical personnel below the level of technologist shall be determined by the director to be fully qualified for all assigned technical duties.

(c) Notwithstanding any other provision of this chapter, an individual who has been employed in a clinical laboratory as a technologist prior to the effective date of this chapter may continue to act in that capacity and may not be required to meet the requirements of subsections (a) and (b).

Notes of Decisions

Although the technologist who performed a blood alcohol test did not possess a baccalaureate degree, she had attended college for 3 years, served a 1-year clinical internship and practiced medical technology for the last 17 years, all of which qualified her as a technologist under this section which provides that a person may qualify by education or experience. *Commonwealth v. O'Hayer*, 497 A.2d 649 (Pa. Super. 1985).

Cross References

This section cited in 28 Pa. Code § 5.1 (relating to definitions).

PHYSICAL FACILITIES

§ 5.31. Working space and lighting.

Working space and lighting shall be adequate. Sufficient equipment in good condition and in working order shall be available for the tests performed. A preventive maintenance program for equipment shall be maintained, and appropriate records kept. Adequate fire prevention and other safety factors shall be present which meet applicable local building codes and ordinances.

§ 5.32. Library.

A current library of books and journals shall be available to the director and other personnel to enable them to keep informed of advances in laboratory medicine. Approved procedural manuals for the work performed shall be immediately available to technical personnel in the laboratory working area.

PROCEDURES

§ 5.41. Acceptance and collection of specimens.

(a) Specimens shall be accepted or collected from patients by a clinical laboratory only when tests are requested on the specimens by a member of the healing arts licensed to practice in this Commonwealth, or other persons authorized by statute, or authorized agents of the foregoing.

(b) No specimen shall be collected by an owner, an employe or other person associated with the clinical laboratory except under one of the following conditions:

(1) The person is a member of the healing arts licensed in this Commonwealth or a laboratory director qualified under the Clinical Laboratory Act of 1951 (P. L. 1539) (35 P. S. § 2151 et seq.).

(2) The person is collecting the specimen under the direction of a member of the healing arts licensed in this Commonwealth or a laboratory director qualified under the Clinical Laboratory Act.

(c) This section does not prohibit the transmission of specimens collected as set forth in subsection (b) under the following circumstances:

(1) To another laboratory licensed under the Clincial Laboratory Act.

(2) To a Federal laboratory.

(3) To a laboratory located in another state providing that laboratory has been issued a license or permit in conformity with the Clinical Laboratories Improvement Act of 1967 (35 P. S. § 2151) and related regulations.

(d) The acceptance of specimens submitted by a representative of the Department, or designated agent, for purposes of evaluation of testing procedures is not prohibited.

Notes of Decisions

A blood test performed by a trained phlebotomist under standard hospital procedures under directors of a physician and met the requirements of this section. *Commonwealth v. Dungan*, 539 A.2d 817 (Pa. Super. 1988); appeal denied 559 A.2d 34 (Pa. 1989).

§ 5.42. Transportation of specimens.

Procedures used for transporting specimens from collection points to the testing facilities of the clinical laboratory shall be such that the physical integrity and composition of the specimen remain intact, and changes do not occur in the specimen which will interfere with the validity of subsequent results. This

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includes factors of time, temperature and other environmental factors which are critical to the preservation of the specimen.

§ 5.43. Identification of specimens.

Every specimen received for testing shall be numbered, listed in an accession book or otherwise marked so that it may be identified definitely and related to the patient, and the submitting member of the healing arts or the referring laboratory. An appropriate dated record of its receipt, disposition and examination, findings obtained, and charges assigned shall be made and kept on file for the minimum period required by statute. The records shall be available for inspection by authorized representatives of the Department.

§ 5.44. Examination of specimens.

(a) No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and examination, when applicable, or other reason sufficient to render the findings of doubtful validity.

(b) No specimen of excised tissue shall be subjected to pathological examination except by a person qualified in the field of anatomic pathology. No specimen of exfoliated tissue or cells shall be examined except under the supervision and review of a person qualified in cytopathology. Ten percent of negative cytology preparations and positive or suspicious preparations shall be reviewed by a person qualified in cytopathology. Technical procedures employed in a laboratory shall be the standard procedures which are generally accepted and approved by the Department. Proof that procedures varying from those commonly employed in laboratory practice are accurate may be required by the Department.

§ 5.45. Onsite testing.

A clinical laboratory shall be prepared during the normal working hours to accept, perform and report promptly on specimens submitted by the Department for purpose of testing the adequacy and accuracy of its procedures.

§ 5.46. Reagents and equipment.

Reagents, procedures or equipment which have been demonstrated to be inadequate for clinical laboratory use as evidenced by reliable data from generally acceptable scientific testing and evaluating sources shall be prohibited for use by clinical laboratories upon specific notification by the Department. Also, reagents, equipment and procedures which do not have substantial proof of efficacy either by trial or extended use experience shall be prohibited for routine use.

Notes of Decisions

Inasmuch as each time it sent in proficiency test results, hospitals had notified Department of Health that it was using a particular type of machine, and inasmuch as the Department had not notified the hospital, under this section, that use of the machine was prohibited, the court could find that the equipment was acceptable. *Commonwealth v. O'Hayer*, 497 A.2d 649 (Pa. Super. 1985).

Cross References

This section cited in 28 Pa. Code § 5.103 (relating to blood tests for blood alcohol content).

§ 5.47. Report of findings.

Reports of clinical laboratory findings shall be made only to the person submitting the specimen or requesting the analysis, or his authorized agent. Nothing in this section shall prohibit the issuance of reports of clinical laboratory findings to town, city, borough or Commonwealth health officials as required by statute or the inspection or impounding of records of the reports by an authorized representative of the Department.

§ 5.48. Disclosure of charges.

A notification of charges for laboratory tests performed for the patient shall be sent to the patient by the clinical laboratory unless the patient has been billed directly or otherwise notified of the charges by the laboratory.

§ 5.49. Reportable diseases.

The director of a clinical laboratory shall report to the Department all laboratory findings which indicate the presumptive presence of any disease required to be reported by the provisions set forth in § 27.22 (relating to reporting of cases by clinical laboratories), or as required by other statutes or regulations of the Commonwealth or by Federal statutes.

§ 5.50. Approval to provide special analytical services.

(a) The Department will approve qualified laboratories to perform certain specialized laboratory services. The Department's Bureau of Laboratories will, from time to time, establish prerequisite requirements for admission to approval programs based on an evaluation of the personnel, equipment and procedures employed in the applicant laboratory. After the prerequisite requirements are satisfied, admission to approval programs will require demonstration of acceptable capability in the analysis of test samples. Continued approved status will require satisfactory performance in periodic evaluations conducted to monitor the reliability of participating laboratories.

(b) Lists of laboratories approved under this section to provide special analytical services will be prepared semiannually and will contain the names, addresses and directors of the facilities. Only approved facilities are permitted to offer the specified determinations to clients in this Commonwealth. If an approval

is revoked or limited for reasons of unsatisfactory performance, reinstatement of approval will require demonstration of proficiency over a testing period not to exceed 6 months.

Source

The provisions of this § 5.50 adopted January 27, 1978, effective January 28, 1978, 8 Pa.B. 247.

Notes of Decisions

This section pertains to laboratories and equipment that are approved by the State Health Department to analyze the amount of alcohol in a person's blood and this section satisfies the requirements of 75 Pa.C.S. § 1547 addressing the chemical tests used to determine blood-alcohol content. *Commonwealth v. Bullock*, 518 A.2d 824 (Pa. Super. 1986); appeal denied 531 A.2d 427 (Pa. 1987).

Cross References

This section cited in 7 Pa. Code § 203.73 (relating to testing); 7 Pa. Code § 203.74 (relating to test results); 28 Pa. Code § 5.102 (relating to equipment and methods for laboratory analysis of breath samples); 28 Pa. Code § 5.103 (relating to blood tests for blood alcohol content); 58 Pa. Code § 15.1 (relating to definitions); 58 Pa. Code § 188.3 (relating to testing); and 58 Pa. Code § 188.4 (relating to test results).

RECORDS

§ 5.51. Retention of reports.

Each clinical laboratory shall keep a record of the results of tests performed on each specimen. In cases in which the clinical laboratory is part of a hospital, the permanent laboratory record may be a part of the patient's medical record.

§ 5.52. Contents of records.

Each clinical laboratory shall have a readily available record indicating the daily accession of specimens containing the following information:

(1) The laboratory number identifying the specimen.

(2) The identification of the person from whom the specimen was taken. Specimens received by mail shall be accompanied by the name and address of the patient from whom the specimen was taken.

(3) The name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory who submitted the specimen. Hospitals may follow their normal procedures associated with requests and records.

(4) The date and hour the specimen was collected by the licensed practitioner or other authorized person.

(5) The date and hour the specimen was received in the laboratory and date test was completed.

(6) The condition of the specimen when received that is, broken, leaked, hemolyzed, turbid, satisfactory and so forth.

(7) The analysis performed.

(8) The result of the laboratory test.

(9) The date a required report was sent to the Department, under §§ 27.2—27.4 and 27.22, or other agencies in accordance with other statutes or provisions.

(10) The charges issued to the patient or his authorized agent for the laboratory services performed.

Notes of Decisions

Effect of Failure to Record Information

The requirements of § 5.52(6) are only for recordkeeping and do not relate to the test procedures themselves. The appellant only alleges that the condition of the sample was not recorded. This did not create an added burden upon the Commonwealth to provide additional evidence of reliability of the blood alcohol content. *Commonwealth v. Demark*, 800 A.2d 947 (Pa. Cmwlth. 2002).

§ 5.53. Confidentiality.

Records and reports of examinations of specimens shall be confidential.

Notes of Decisions

Argument by a defendant, charged with driving under the influence, that medical purposes blood test should have been suppressed by hospital personnel in accordance with confidentiality regulations failed because the regulations governing confidentiality were subject to the exceptions contained in the Motor Vehicle Code which provide that no hospital or medical personnel may refuse to perform or provide the results of a blood alcohol test when requested by a police officer. *Commonwealth v. Hipp*, 551 A.2d 1086 (Pa. Super. 1988).

QUALITY CONTROL AND PROFICIENCY TESTING

§ 5.61. Quality control.

(a) Quality control procedures in chemistry, microbiology, hematology and other laboratory specialties shall be those approved by the Department.

(b) A degree of accuracy, specificity and precision satisfactory to the Department shall be shown in quality control records at all times.

§ 5.62. Results of proficiency tests.

(a) Results of proficiency tests shall be maintained in the acceptable ranges statistically determined for each evaluation. Failure of a laboratory to satisfactorily perform in a proficiency test may be cause for revocation of approval of the specific tests involved.

(b) If a permit is revoked or limited for reasons of unsatisfactory performance, reinstatement of approval shall require demonstration of proficiency over a testing period, not to exceed 6 months.

ETHICAL PRACTICE

§ 5.71. Restrictions on solicitation.

No employe or representative of a laboratory, either personally or through an agent, may solicit referral of specimens to his or any other laboratory in a manner which offers or implies an offer of rebates to persons submitting specimens or other feesplitting inducements. This applies to contents of fee schedules, bill-

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ing methods or personal solicitation. No person involved in the submission of specimens may receive payment or other inducement by the laboratory or its representative.

§ 5.72. List of tests and fee schedules.

(a) No blanket contract fee service may be made. Per specimen cost may vary with volume, but the fee schedule shall be clearly stated, and offered equally to all persons using the services of the laboratory. Except for cost adjustments due to volume, only a single fee schedule shall be maintained and applied by a licensed laboratory.

(b) A copy of each list of tests and each fee schedule issued by a laboratory shall be placed on file with the Department prior to issuance, and changes in the schedules filed within 10 days of issuance. The record of fees shall include individual fees, contract fees and special volume prices.

(c) It shall be an unethical practice for a laboratory not to follow the practices in § 5.48 (relating to disclosure of charges).

§ 5.73. Advertisements.

(a) Advertisements shall be reviewed by the Department and approved prior to publication. Failure of the Department to respond within 10 days after receipt of a submission shall constitute an approval. Advertising is permissible in official media if it is of an ethical nature and does not contain misleading statements or claims of unusual superiority. Personal solicitation by an owner or his agent shall be considered as advertising within the meaning of this section. No laboratory may advertise services which are not performed on its own premises. Advertising to the general public is not permitted.

(b) A laboratory requesting a permit shall submit with its application copies of all advertising, telephone listings, letterheads, cards and the like.

(c) Laboratories presently operating under permit shall also submit copies of the advertising, telephone listing and the like to the Department prior to publication.

(d) Signs of a descriptive character designed to identify the laboratory premises or access thereto are permissible except when their content, size or location is unethical or when they constitute a form of advertising of clinical laboratory procedures to the lay public.

EXEMPTIONS

§ 5.81. Federal laboratories.

Laboratories operated by the Federal government, and located in Federal installations in this Commonwealth are exempt from this chapter.

§ 5.82. Research laboratories.

Laboratories operated solely for research and teaching, and conducting analyses, the results of which are not used for clinical application, are exempt from the provisions of this chapter.

§ 5.83. Laboratories outside the Commonwealth.

A laboratory located outside the Commonwealth may solicit and receive specimens originating within the Commonwealth if it has a currently valid license issued under the provisions of section 353 of the Clinical Laboratory Improvement Act of 1967 (42 U.S.C.A. § 263), and applicable regulations and, it complies with all regulations which exceed or differ from those of the Federal statute.

Source

The provisions of this § 5.83 amended August 15, 1975, 5 Pa.B. 2129. Immediately preceeding text appears at serial page (16829).

DENIAL, SUSPENSION, REVOCATION OF PERMITS

§ 5.91. Failure to maintain standards.

A permit shall be denied to a laboratory applying for same and a permit shall be suspended or revoked in the case of laboratories already operating, for failure to maintain proper standards of accuracy, for unethical practice, unethical advertising, or for any other cause deemed adequate by the Department, including failure to render required reports within the reasonable time limits set.

Cross References

This section cited in 28 Pa. Code § 125.1 (relating to clinical and anatomical pathology services).

§ 5.92. Change of director or change of location.

Permits shall become void upon change of director and also upon removal of the laboratory to other quarters.

Cross References

This section cited in 28 Pa. Code § 125.1 (relating to clinical and anatomical pathology services).

§ 5.93. Revocation of permit.

The following are prima facie reasons for the revocation of a permit:

(1) Dishonest reporting or consistent error based on faulty techniques.

(2) Permitting unauthorized persons to perform the technical procedures or to sign reports.

(3) Proof that a holder of a permit has made false statements on his application for a permit.

(4) The advertising of clinical laboratory procedures to the lay public in magazines, newspapers, directories, circulars, signs and the like.

(5) Knowingly accepting an assignment for a clinical laboratory test or a specimen from and the rendering of a report thereon to a person, other than the patient, not authorized to submit the specimen or assignment.

(6) The adjudication of insanity or mental illness involving personnel responsible for the direction of the laboratory.

(7) Violations of another provisions of this chapter, or of the statutes under which they are adopted.

Cross References

This section cited in 28 Pa. Code § 125.1 (relating to clinical and anatomical pathology services).

§ 5.94. Hearings and appeals.

If a license is denied or revoked, the applicant or holder of the license is entitled to the rights of hearings and appeals provided for in the Clinical Laboratory Act (35 P. S. §§ 2151—2165) and other provisions of statutes related to 2 Pa.C.S. §§ 501—508 and 701—704 (relating to practice and procedure of Commonwealth agencies and judicial review of Commonwealth agency action) and the Pa.R.C.P.

Cross References

This section cited in 28 Pa. Code § 125.1 (relating to clinical and anatomical pathology services).

EQUIPMENT TO DETERMINE BLOOD ALCOHOL CONTENT UNDER THE VEHICLE CODE AND THE FISH AND BOAT CODE

§ 5.101. Purpose.

The purpose of §§ 5.101—5.104 (relating to equipment to determine blood alcohol content under the Vehicle Code and the Fish and Boat Code) is to satisfy the requirements of 75 Pa.C.S. § 1547(c) and (k) and 30 Pa.C.S. § 5125(c) and (k) (relating to chemical testing to determine amount of alcohol or controlled substance).

Authority

The provisions of this § 5.101 issued under the Fish and Boat Code, 30 Pa.C.S. § 5125.

Source

The provisions of this § 5.101 adopted January 27, 1978, effective January 28, 1978, 8 Pa.B. 247; amended through July 27, 1984, effective July 30, 1984, 14 Pa.B. 2759. Immediately preceding text appears at serial page (89897).

Cross References

This section cited in 58 Pa. Code § 51.51 (relating to chemical tests); and 58 Pa. Code § 131.5 (relating to chemical tests).

§ 5.102. Equipment and methods for laboratory analysis of breath samples.

Only equipment and methods approved by the Department may be used for the laboratory analysis of breath samples. Laboratories performing these analyses shall be licensed and specifically approved for blood alcohol analysis in accordance with §§ 5.50 and 5.103 (relating to approval to provide special analytical services; and blood tests for blood alcohol content).

Authority

The provisions of this § 5.102 issued under section 2102 of The Administrative Code of 1929 (71 P. S. § 532); and the Vehicle Code, 75 Pa.C.S. § 1547(c).

Source

The provisions of this § 5.102 amended through August 31, 1984, effective September 1, 1984, 14 Pa.B. 3156. Immediately preceding text appears at serial pages (89897) and (89898).

Cross References

This section cited in 28 Pa. Code § 5.101 (relating to purpose); 58 Pa. Code § 51.51 (relating to chemical tests); and 58 Pa. Code § 131.5 (relating to chemical tests).

§ 5.103. Blood tests for blood alcohol content.

Equipment used for blood analysis to determine the amount of alcohol in a person's blood which performs the analysis by means of gas chromatography, enzymatic procedures, distillation procedures or diffusion procedures is approved by the Department provided that:

(1) The equipment is located within a clinical laboratory currently licensed by the Department.

(2) The particular brand or model of equipment used and a reagent or procedures relating thereto have not been prohibited by specific notification of the Department under § 5.46 (relating to reagents and equipment).

(3) A clinical laboratory performing blood analyses with the equipment has in effect an approval to provide the special analytical services under § 5.50 (relating to approval to provide special analytical services).

Source

The provisions of this § 5.103 adopted January 27, 1978, effective January 28, 1978, 8 Pa.B. 247.

Notes of Decisions

A blood serum analysis was erroneously suppressed since the trial court improperly concluded that regulations regarding blood alcohol testing had not been promulgated. *Commonwealth v. Dagon*, 605 A.2d 360 (Pa. Super. 1992).

A driver's failure to provide two vials of blood for alcohol testing purposes under standard procedure of local police department, was not refusal to complete blood test for purposes of implied consent provisions since the Department failed to promulgate regulations for determining what constitutes completion of a blood test. *Murray v. Commonwealth*, 598 A.2d 1356 (Pa. Cmwlth. 1991).

Testimony from a hospital medical technologist regarding the hospital's procedure for updating its renewal certificate from the Department of Health was sufficient to meet the licensing requirements of this section. *Commonwealth v. Dungan*, 539 A.2d 817 (Pa. Super. 1988).

A blood test utilizing an enzyme reaction was an analysis by ''enzymatic procedures'' which met the requirements of this section. *Commonwealth v. Dungan*, 539 A.2d 817 (Pa. Super. 1988); appeal denied 559 A.2d 34 (Pa. 1989).

Inasmuch as each time it sent in proficiency test results, hospitals had notified Department of Health that it was using a particular type of machine, and inasmuch as the Department had not notified the hospital, under this section, that use of the machine was prohibited, the court could find that the equipment was acceptable. *Commonwealth v. O'Hayer*, 497 A.2d 649 (Pa. Super. 1985).

Cross References

This section cited in 28 Pa. Code § 5.101 (relating to purpose); 28 Pa. Code § 5.102 (relating to equipment and methods for laboratory analysis of breath samples); 58 Pa. Code § 51.51 (relating to chemical tests); and 58 Pa. Code § 131.5 (relating to chemical tests).

§ 5.104. Prearrest breath tests for blood alcohol content.

(a) *Equipment approval requirements.*

(1) The Department will approve prearrest breath testing devices for use by police officers in conducting preliminary alcohol determinations on persons suspected of driving while under the influence of alcohol. Until performance standards for prearrest breath testing devices are promulgated by regulation, manufacturers who desire interim approval of their devices shall file the following information with the Department:

(i) A complete description of the device, including its principle of operation.

(ii) An operator's manual for the device.

(iii) A maintenance and repair manual for the device, if applicable, including diagrams and lists of component parts.

(iv) Performance data derived from studies conducted by or for the manufacturer to support claims relating to the reliability of the device.

(v) The names and addresses of law enforcement agencies in this Commonwealth who have purchased the device. Manufacturers shall provide to the Department, on an annual basis, the names and addresses of new purchasers to whom the devices are sold.

(vi) A list and complete description, including applicable manuals, for breath simulators or other accessories intended for use with the prearrest breath testing device.

(vii) A list of authorized distributors and service representatives for the prearrest breath testing device.

(viii) The data and results of reviews or studies conducted by other State or Federal agencies, including certification or approval, if available.

(2) When the filing requirements in paragraph (1) have been met and the Department is satisfied that the information supplied by the manufacturer is complete, adequate and responsive; that the device has been properly tested;

that the device is reliable and readily available; and that the device can be adequately serviced, the device will be issued an interim approval for use in this Commonwealth. The interim approval will remain in effect until performance standards are promulgated by regulation, or until unsatisfactory performance is demonstrated.

(b) *Approved equipment list.* Prearrest breath testing devices which meet subsection (a) will be placed on a list of approved equipment for preliminary breath alcohol testing purposes. This list will be revised semiannually. A certified copy of the list will be available upon request at the Bureau of Laboratories.

(c) *Application for approval.* Manufacturers of prearrest breath testing devices who are seeking approval from the Department for their instruments to be used by law enforcement officials shall submit information specified in subsection (a)(1) to: Division of Chemistry and Toxicology, Bureau of Laboratories, Department of Health, Pickering Way & Welsh Pool Road, Lionville, Pennsylvania 19353, (215) 363-8500.

Source

The provisions of this § 5.104 adopted May 11, 1984, effective May 12, 1984, 14 Pa.B. 1644.

Cross References

This section cited in 28 Pa. Code § 5.101 (relating to purpose); and 58 Pa. Code § 51.51 (relating to chemical tests); and 58 Pa. Code § 131.5 (relating to chemical tests).

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