

**Health Services**

Cap. 44.

**HEALTH SERVICES (PATHOLOGICAL  
LABORATORIES) REGULATIONS, 1976**

S.I.

1976/105.

S.I.

**Authority:** These regulations were made on 5th April, 1976 by the Minister under section 10 of the *Health Services Act*.

1978/111.

S.I.

1985/19.

**Commencement:** 5th April, 1976.

1. These Regulations may be cited as the *Health Services Pathological Laboratories) Regulations, 1976*.

2. For the purposes of these regulations

“classes of tests” means tests or groups of tests requiring the use of knowledge and skills in any science specified in the First Schedule each such science comprising a class for the purposes of these regulations;

First

Schedule.

“Committee” means the Pathological Laboratories Advisory Committee appointed by the Minister under section 8 of the *Health Services Act* for the purpose of advising him on matters relating to pathological laboratories;

Cap. 44.

“dental practitioner” has the meaning assigned to it by section 2 of the *Dental Registration Act*;

Cap. 367.

“inspector” means a person assigned by the Minister to be an inspector pursuant to regulation 12;

“laboratory director” means a person charged with responsibility for

(a) the administration of the scientific and technical operation of a pathological laboratory;

(b) the supervision of tests; and

(c) the reporting of the results of tests;

“laboratory supervisor” means a person who, under the general supervision of a laboratory director, supervises pathological laboratory personnel and performs tests requiring special scientific skills;

**THE LAWS OF BARBADOS**

Printed by the Government Printing Department, Bay Street, St. Michael,  
by the authority of the Government of Barbados

“laboratory technician” means a person who, under direct supervision of a laboratory supervisor, performs tests that require limited technical skills and responsibilities;

“laboratory technologist” means a person who, under general supervision, performs tests that require the exercise of independent judgement;

“laboratory trainee” means a person who is employed in a pathological laboratory for the purpose of being trained in the operations and procedures performed in a pathological laboratory;

Cap. 371.

“medical practitioner” has the meaning assigned to it by section 2 of the *Medical Registration Act*;

“operator” means a person, including a corporation, having charge or control of a pathological laboratory;

“pathological laboratory” or “laboratory” means an institution, building or place in which operations and procedures for the examination of specimens taken from the human or other animal body are performed to obtain information for the diagnosis, prophylaxis or treatment of disease;

“test” means a procedure for carrying out a laboratory examination;

Cap. 374.

“veterinary surgeon” means a person whose name appears on the Register of Veterinary Surgeons pursuant to section 4 of the *Veterinary Surgeons Act*.

S.I.

1985/19.

3. (1) No person shall establish a pathological laboratory unless he applies for and obtains the approval of the Minister in writing to do so.

(2) A person who desires to obtain a licence for the purposes of paragraph (1) shall make application in writing in such form as the Minister determines, giving the following details

- (a) the name and address of the owner or operator;
- (b) the name, address and qualifications of the director;
- (c) the name, address and qualifications of the supervisor;
- (d) the qualifications of any laboratory technologists or technicians to be employed;

- (e) the classes of tests which it is proposed to carry out in the laboratory;
- (f) whether the administration of the scientific and technical operations of the laboratory are under the control of a laboratory director; and
- (g) what staff is employed in the laboratory to ensure proper performance of the tests for which the licence is sought.

**3A.** No person shall operate a pathological laboratory except under the authority of a licence issued by the Minister. S.I.  
1985/19.

**3B.** A person who desires to obtain the Minister's approval under regulation 3 or a licence for the purposes of regulation 3A shall make application in writing in such form as the Minister determines giving the following details:

- (a) the name and address of the owner or operator;
- (b) the name, address and qualifications of the director;
- (c) the name, address and qualifications of the supervisor;
- (d) the qualifications of any laboratory technologists or technicians to be employed;
- (e) the classes of tests which it is proposed to carry out in the laboratory;
- (f) whether the administration of the scientific and technical operations of the laboratory are under the control of a laboratory director; and
- (g) what staff is employed in the laboratory to ensure proper performance of the tests for which the licence is sought.

**4.** (1) The Minister may refer any application made under regulation 3, 3A or 3B to the Committee for its advice.

(2) The Committee shall, upon an application being referred to it by the Minister, carry out such investigations in respect of such application as it thinks fit, and upon completion of such investigations submit, together with its advice, a report respecting its investigations.

(3) The Minister may, after considering the report and advice of the Committee S.I.  
1985/19.

Third  
Schedule.

- (a) in respect of an application for the establishment of a pathological laboratory, grant his approval;
- (b) in respect of an application for the operation of a pathological laboratory, on the payment of a fee of \$500 by the applicant, issue to the applicant a licence in the form specified in the *Third Schedule*.

(4) A licence issued under paragraph (3) expires on 31st December of the year in which it is issued and is renewable during the month of January of each year on payment of a fee of \$500.

(5) Where a licence is issued under paragraph (3) on a date subsequent to 31st January of any year, the fee payable under that paragraph shall be reduced by deducting therefrom \$41.50 in respect of each month which has expired prior to the date of the issue of any licence in any such year.

S.I.  
1985/19.

5. (1) The Minister may, if he is advised by the Committee that

- (a) there is no public need for the laboratory that the applicant proposes to establish, refuse to give his approval for the establishment of that laboratory;
- (b) the applicant is not competent to operate a laboratory in accordance with these regulations, refuse to issue a licence;
- (c) the equipment or the premises of the laboratory are not suitable for the carrying out of the tests required to be carried out in the laboratory, refuse to issue a licence; or
- (d) the staff are not competent to perform the tests for which the licence is sought, refuse to issue a licence.

(2) Paragraph (1) (a) does not apply to the issue of a licence in respect of a laboratory in operation immediately before the 5th April 1976 if the applicant for such a licence satisfies the requirements of sub-paragraphs (1) (b) and (c).

6. A licence issued under regulation 4 (3)

- (a) shall contain
  - (i) the date of issue of such licence.

- (ii) the name and address of the owner or operator of the laboratory,
  - (iii) the name, if any, and the address of the laboratory,
  - (iv) the name, address and qualifications of the director, and
  - (v) the classes of test authorised to be performed under that licence; and
- (b) shall be kept constantly exhibited in a conspicuous place in the laboratory to which it relates; and
- (c) is not transferable.

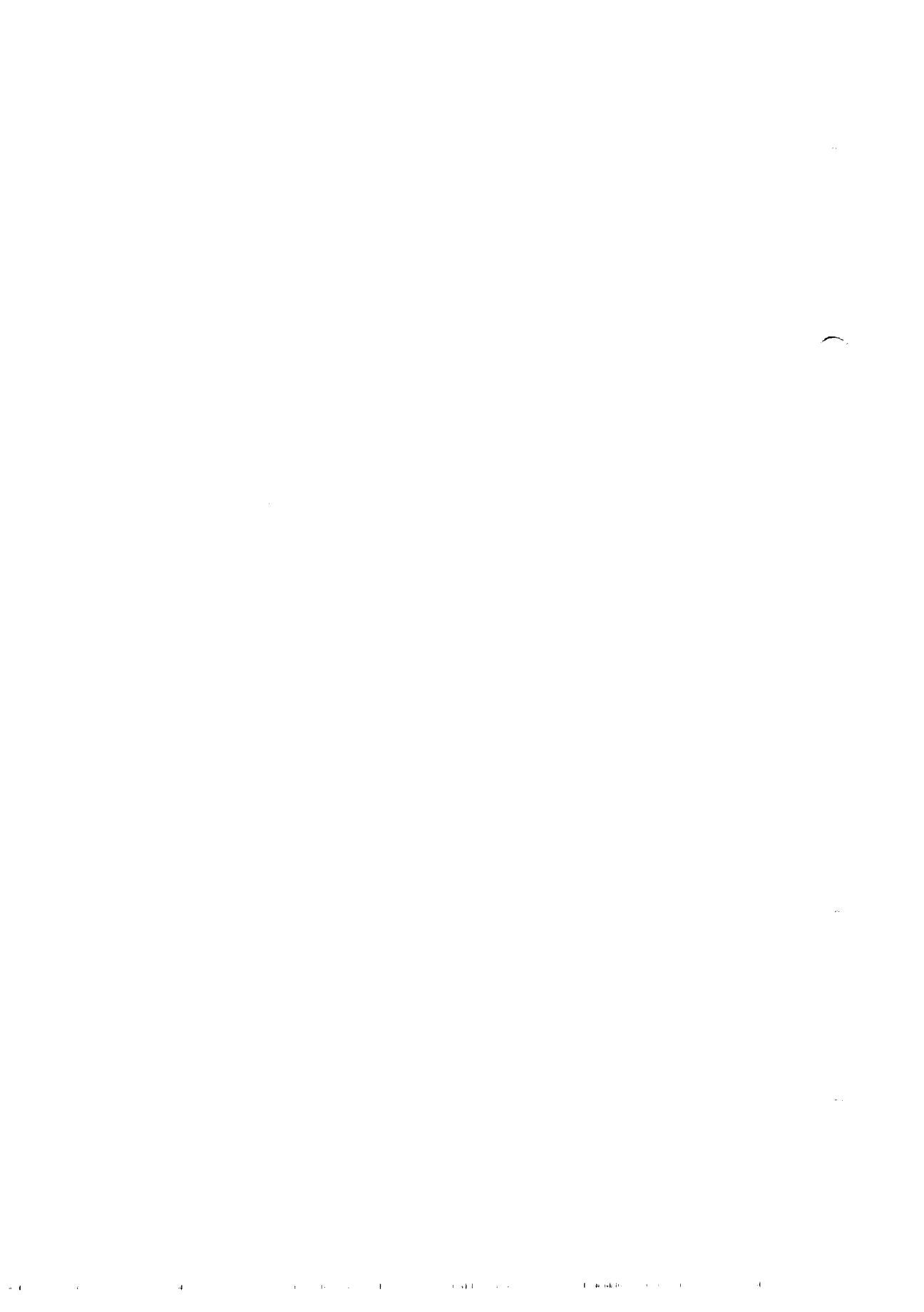
7. (1) The Minister may suspend for such time as he thinks fit, or cancel, a licence issued under these regulations where the operator

- (a) fails or refuses to comply with these regulations; or
- (b) is unable to satisfy regulation 5(1) (b) or (c).

(2) Where a licence is cancelled or suspended, the person to whom the licence was issued or the person in charge of the laboratory shall immediately deliver up the licence to the Minister.

8. (1) Subject to regulation 9, no person shall, after 5th April 1976 be employed as

- (a) a laboratory director unless
  - (i) he is a medical practitioner having not less than 2 years post-graduate training in a laboratory approved by the Committee, or
  - (ii) he has obtained from a University or other institution, approved by the Committee, a degree or diploma in the chemical, physical or biological



- subjects practised in that laboratory and has not less than 2 years post-graduate training in a laboratory approved by the Committee;
- (b) a laboratory supervisor unless—
- (i) he is a medical practitioner having not less than 1 year's post-graduate experience in a laboratory approved by the Committee,
  - (ii) he has obtained from a University or other institution, approved by the Committee, a degree or diploma in the chemical, physical or biological subjects practised in that laboratory and has not less than 1 year's post-graduate experience in a laboratory approved by the Committee, or
  - (iii) he is a qualified laboratory technologist having not less than 5 years experience in a pathological laboratory approved by the Committee;
- (c) a laboratory technologist, unless—
- (i) he has obtained from a University or other institution approved by the Committee a degree or diploma in the chemical, physical or biological subjects practised in that laboratory; and
  - (ii) he has not less than 1 year's experience as a laboratory technician in a laboratory approved by the Committee;
- (d) a laboratory technician unless—
- (i) he has been apprenticed or served for not less than 2 years as a laboratory trainee in a pathological laboratory approved by the Committee; and
  - (ii) he has obtained a certificate of competence in the chemical, physical or biological subjects practised in that laboratory from an institution approved by the Committee; or
- (e) a laboratory trainee unless he possesses the qualifications at any time specified for laboratory trainee by the West Indian Society of Medical Technologists or such other institution as the Minister approves.
- (2) No person shall be employed—

**THE LAWS OF BARBADOS**

- (a) as a laboratory director or laboratory supervisor in more than 2 laboratories at any one time; or
- (b) as a laboratory technologist, laboratory technician or laboratory trainee in more than 1 laboratory at any one time.

**9.** A person who at the commencement of these regulations does not satisfy the requirements of regulation 8(1) may be exempted from those requirements if—

- (a) he is employed as a laboratory director, laboratory supervisor, laboratory technologist or laboratory technician; and
- (b) the Minister is satisfied that he is competent to perform the functions required of a person so employed.

**10.** The operator of a pathological laboratory shall—

- (a) within 14 days of any change in the qualified personnel employed in that laboratory, inform the Minister in writing of such changes; and
- (b) ensure that the staff of the laboratory—
  - (i) perform in the laboratory those tests specified in the licence,
  - (ii) examine and test specimens from humans, only when requested to do so by a medical or dental practitioner, or from other animals only when requested to do so by a veterinary surgeon,
  - (iii) report the results of any test to the person at whose request it was carried out,
  - (iv) report to the Chief Medical Officer any positive laboratory findings in human or other animals referable to the diseases specified in the Second Schedule,
  - (v) establish a quality control programme of which the Minister, on the advice of the Committee, approves,
  - (vi) keep a record of each test carried out in the laboratory for a period of not less than 2 years and make such record available for inspection by an inspector at all reasonable times, and



- (vii) analyse and report upon any samples submitted for testing to the laboratory by or on behalf of the Chief Medical Officer.

11. No person shall advertise or cause to be advertised the services of any laboratory, but a person may notify any medical practitioner, dental practitioner or veterinary surgeon of

- (a) the name and address of a laboratory; and
- (b) the tests that are performed in that laboratory.

12. (1) The Minister may assign such public officers as he thinks fit to be inspectors to assist in the enforcement of these regulations.

(2) The Minister shall issue to every inspector assigned under paragraph (1) a certificate of his assignment, and every inspector in executing his duties under these regulations shall produce his certificate of assignment upon request of a laboratory operator or supervisor.

(3) An inspector may, at all reasonable times, enter any laboratory and inspect the premises, operations, records and materials which have been tested or are to be tested, to ensure that these regulations are complied with.

(4) An inspector may, upon giving a receipt therefor, seize and detain any material or record inspected by him under paragraph (3) for the purposes of his duties.

(5) Any person who

- (a) assaults, resists, obstructs or intimidates an inspector in the execution of his duty;
- (b) uses indecent, abusive, or insulting language to an inspector in the execution of his duty;
- (c) interferes with or hinders an inspector in the execution of his duty;
- (d) by any gratuity, bribe, promise or other inducement prevents or attempts to prevent an inspector from carrying out his duty;
- (e) without the authority of an inspector removes, alters or interferes in any way with any material or record seized under paragraph (4); or
- (f) contravenes any of these regulations,

THE LAWS OF BARBADOS

S.I.  
1985/19.  
S.I.  
1978/111.

is guilty of an offence and liable on summary conviction to a fine not exceeding \$5 000 or imprisonment for a term not exceeding 12 months, or both, and in the case of a contravening offence, to a further fine not exceeding \$200 for each day or part thereof during which the offence continues after a conviction is first obtained.

**13.** These regulations do not apply to

- (a) any hospital, institution or place maintained or controlled by a Minister or by a Board or Committee appointed by a Minister; or
- (b) any procedure carried out by a medical practitioner, dental practitioner or veterinary surgeon for the purpose of the diagnosis of disease and treatment of his patients.

---

FIRST SCHEDULE

*(Regulation 2)*

Microbiology including bacteriology, virology, mycology and  
Parasitology  
Serology  
Haematology  
Chemistry  
Pathology  
Cytology  
Radioisotopic assays  
Immunohaematology

SECOND SCHEDULE

*(Regulation 10)*

Actinomycosis  
Anthrax  
Cholera  
Dengue  
Diphtheria  
Dysentery (Amoebic)  
Dysentery (Bacillary)  
Infectious Hepatitis  
Influenza  
Leprosy  
Leptospirosis  
Malaria  
Meningococcal Meningitis



