

SUBSIDIARY LEGISLATION 458.25

LICENSING OF PRIVATE MEDICAL DIAGNOSTIC LABORATORIES

9th July, 1996

LEGAL NOTICE 133 of 1996, as amended by Legal Notice 426 of 2012.

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| <p>1. The title of these Regulations is Licensing of Private Medical Diagnostic Laboratories Regulations.</p> | Title. |
| <p>2. In these Regulations, unless the context otherwise requires -</p> | Interpretation. |
| <p>"the Act" means the Health Care Professions Act;</p> | Cap. 464. |
| <p>"authorised person" means a person authorised by the Minister to act on his behalf;</p> | |
| <p>"good laboratory practice" includes the compliance at all times with the ethical standards and with laws and regulations governing the professions related with laboratory practice, as well as compliance with international standards for procedures, practices and methods used in a laboratory;</p> | |
| <p>"laboratory" means a private medical diagnostic laboratory, and includes any facility, building or otherwise, used for the purpose of biological, microbiological, serological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, or other examination of material derived from the human or animal body, or for the purpose of providing information for the diagnosis, prevention or treatment of any disease, condition or impairment of health, or for the assessment of the state of health of a person or animal, but does not include a government laboratory;</p> | |
| <p>"Minister" means the Minister responsible for health.</p> | |
| <p>3. (1) No licence for operating a laboratory under article 98 of the Medical and Kindred Professions Ordinance may be granted or renewed unless such laboratory complies with the provisions of these regulations.</p> | Laboratory to comply with these regulations.
Cap. 31. |
| <p>(2) No licence under the said article 98 of the Medical and Kindred Professions Ordinance may be issued for any laboratory except in respect of a premises used for medical laboratory tests and procedures.</p> | |
| <p>4. (1) An application for the issue or renewal of a licence for a laboratory shall be made to the Minister in writing:</p> | Application for a licence.
Amended by:
L.N. 426 of 2012. |
| <p>Provided that an application has been filed before the date of these regulations, it shall be considered to have been filed according to these regulations.</p> | |
| <p>(2) On making an application under subregulation (1), the applicant shall present together with the application the information specified hereunder:</p> | |

- (a) a comprehensive list of all the tests and other activities carried out or intended to be carried out at such laboratory;
- (b) a list of all the staff that are employed or to be employed at the laboratory, including their name and surname, a legally valid identification document number, permanent address, date of birth, date of employment, academic qualifications and duties and responsibilities each employee shall have;
- (c) a list of equipment that is used, or intended to be used on the premises;
- (d) a list of animals that are kept or used, or intended to be kept or used for such tests;
- (e) the policy and procedures for quality control and safety;

Provided that the Minister or any authorised person may request of the applicant any additional information and more specific information that is deemed to be related with the granting of the licence.

Refusal of licence.

5. (1) The Minister may refuse to issue or renew a licence in respect of a laboratory if -

- (a) the applicant, or any person employed or proposed to be employed by the applicant at the laboratory, is not of good conduct or that the technical staff is not suitably qualified; or
- (b) for reasons connected with the situation, construction, state of repair, safety, accommodation, staffing or equipment, the premises are not fit to be used as a laboratory; or
- (c) the laboratory or any premises in connection therewith are used or proposed to be used for purposes which are not related to the laboratory, or are in any way improper, unethical or not lawful; or
- (d) the laboratory or any premises used in connection therewith consist of or include works executed in contravention of the provisions of the Development Planning Act; or
- (e) the practice at the laboratory is not, or will not be, under the supervision of a person indicated in regulation 6; or
- (f) the management and control of the laboratory is not likely to be adequate.

Cap. 356.

(2) Where a licence has been refused or is not renewed or has been withdrawn, the applicant or licensee, as the case may be, may within thirty days of receipt of notice of refusal, non-renewal or withdrawal of licence, appeal to the Tribunal appointed under regulation 5(2) of the Licensing of Private Medical Clinics Regulations.

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6. Every licensee shall ensure that medical laboratory tests are carried out by, or under the professional direction, supervision and responsibility of, a biochemist, microbiologist or other pathologist, or a toxicologist, as the case may be, or a medical practitioner or scientist qualified to assume professional, scientific, consultative, organisational and administrative responsibility for the service.

Professional direction, supervision and responsibility for tests.

7. (1) The licence certificate shall specify the category and types of tests that may be carried out at the premises as may be determined by the Minister to be reasonable in accordance with good laboratory practice taking into account the size of the laboratory and the facilities available.

Category and types of tests.

(2) The licensee shall ensure that no tests other than those referred to in subregulation (1) shall be carried out at the laboratory unless and until such test has been approved by the Minister.

8. (1) The licensee shall keep and maintain an updated register in connection with all tests carried out at the laboratory, which register shall, in respect of each patient, include the following information:

Registers and records.
Amended by:
L.N. 426 of 2012.

- (a) the name and surname, (or initials), a legally valid identification document number, sex, address and date of birth of the patient;
- (b) the name, surname, address and medical registration number of the referring medical practitioner;
- (c) the date when the request was received at the laboratory;
- (d) the type of test requested by the referring medical practitioner;
- (e) the type of test carried out at the laboratory and methods used;
- (f) the name of the microbiologist, biochemist or other pathologist, or toxicologist responsible for the test, as well as the technical person who carried out the test;
- (g) where practicable, the result of the test;

Provided that the requirements in respect of the identity of the patient shall not apply when the blood of a patient is taken for testing for the human immunodeficiency virus, so that this test is carried out in a government laboratory.

(2) The licensee shall also keep records of reports of all results of tests carried out at his laboratory.

- (3) (a) The licensee shall require all persons to whom Part II and Part V of the Act refers, to register their attendance at the laboratory, indicating date and time and whether entering or leaving the laboratory, immediately on entering and immediately before leaving the laboratory, in a register kept for the purpose. The licensee shall transmit the contents of such register to the Ministry or department in such manner as specified by the Minister.

- (b) Where, except in an emergency, a licensee is in wilful breach of the preceding provision of this regulation, such laboratory shall be deemed to be operating without a licence.

(4) The Minister may from time to time prescribe that additional registers be kept as may be deemed necessary to ensure good laboratory practice.

Maintenance and inspection of registers and records.

9. All information entered in the registers referred to in regulation 8, as well as all records, shall be retained by the licensee for a period of not less than two years from the date of the last entry in the register or record:

Provided that in respect of histological tests or any forensic or toxicological tests, the result shall be kept for a period of twenty-five years:

Provided further that results of tests of quality assessment or maintenance shall be kept indefinitely.

Licensee to notify certain diseases.
Amended by:
L.N. 426 of 2012.
Cap. 36.

10. The licensee shall inform forthwith the Superintendent of Public Health of any infectious disease diagnosed at the laboratory, notifiable under the Prevention of Disease Ordinance, as well as of all pathological samples confirmed for malignancy, with the details of name, address and a legally valid identification document number of the patient, as well as the name, address and medical registration number of the referring medical practitioner.

Provision of facilities and services.

11. (1) The licensee shall ensure that there is sufficient space, equipment and facilities for the proper performance, within the medical laboratory, of the required volume of work to ensure that a high standard of accuracy, precision, efficiency and safety is always maintained to the satisfaction of the Minister.

(2) Without prejudice to the generality of subregulation (1), the licensee, having regard to the category of tests performed at the laboratory, shall -

- (a) provide adequate professional, technical, ancillary and other supporting staff;
- (b) provide and maintain adequate laboratory facilities in accordance with good laboratory practice;
- (c) maintain all parts of the building in a good structural state of repair, and, in particular, provide adequate lighting and ventilation, and all necessary safety;
- (d) maintain a high degree of cleanliness and hygiene in all parts of the building;
- (e) take established precautions against the risk of fire and make established arrangements for detecting, containing and extinguishing fires and for the evacuation of staff in the event of such fire. In particular the licensee shall comply with such instructions as may be given by the Commissioner of Police in this respect;

- (f) make appropriate arrangements to the satisfaction of the authorised person for the disposal and incineration of infected swabs and sharps besides other infected material and provide adequate containers for them;
- (g) take all the necessary precautions to ensure the safety, both physical and biological, of all staff on the premises. Moreover, he shall provide and maintain adequate means of protection against occupational hazards, and ensure that all staff is making use of the protection provided.

(3) The licensee shall make available, when so required by the Minister or by any authorised officer, the following written codes of practice and procedures:

- (a) the laboratory's policy for quality control on a daily basis, including accreditation of its tests from an authority that is recognised by the Minister to be appropriate and reliable, with inter-laboratory calibration exercises forming part of this accreditation;
- (b) the laboratory's policy on instrument function checks and preventive maintenance of instruments;
- (c) the laboratory's safety policies to the workers, the patients and the public in general:

Provided that the Minister may from time to time require these codes to be amended and updated as he may deem appropriate.

(4) The licensee shall ensure that the codes referred to in subregulation (3) are strictly adhered to by all persons working in the laboratory.

12. It shall be lawful for any authorised person, to enter at any time of day and night without prior notice, and inspect any premises which are used or suspected to be used with or without a licence as a medical laboratory, and such person shall be given by the person in charge at the time, all assistance requested or implied. The said person in charge shall produce all registers and records available at that time when asked to do so:

Power of inspection.

Provided that where the information requested entails medical confirmation regarding the patients, such information may only be requested by and made available to an authorised person who is a medical practitioner.

13. The licensee shall ensure that all measures be taken to protect the staff and the neighbourhood from any nuisance or danger arising from the activities of the laboratory.

Safety and prevention of danger.

14. These regulations do not apply to the medical tests carried out by the use of medical diagnostic kits intended for home use, irrespective of where these tests are carried out, or in respect of tests carried out by a medical practitioner in his consulting room or at the patient's home, or bedside, using doctor's office equipment in the exercise of his profession.

Non-applicability of regulations.