L.N. 133 of 1996

MEDICAL AND KINDRED PROFESSIONS ORDINANCE (CAP. 31)

Private Medical Diagnostic Laboratories (Licensing) Regulations, 1996

IN exercise of the powers conferred by subsection (3) of section 98 of the Medical and Kindred Professions Ordinance, the Minister for Social Development has made the following regulations:—

Citation.

1. These regulations may be cited as the Private Medical Diagnostic Laboratories (Licensing) Regulations, 1996.

Interpretation.

2. In these regulations, unless the context otherwise requires —

"authorised person" means a person authorised by the Minister to act on his behalf;

"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;

"laboratory" means a private medical diagnostic laboratory;

"Minister" means the Minister responsible for health;

"the Ordinance" means the Medical and Kindred Professions Ordinance;

"private medical diagnostic laboratory" 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.

Laboratory to comply with these regulations.

3. (1) No licence for operating a laboratory under section 98 of the Ordinance may be granted or renewed unless such laboratory complies with the provisions of these regulations.

(2) No licence under the said section 98 may be issued for any laboratory except in respect of a premises used for medical laboratory tests and procedures.

4. (1) An application for the issue or renewal of a licence for a laboratory shall be made to the Minister in writing: Application for a licence.

Provided that where an application for a licence has already been submitted before the coming into force of these regulations, such application shall be deemed to have been made in accordance with these regulations.

(2) On making an application under paragraph (1) of this regulation, the applicant shall present together with the application the information specified hereunder:

(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, Identity Card 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.

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

(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 use 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, 1992; or

Act No. I of 1992.

(e) the practice at the laboratory is not, or will not be, under the supervision of a person indicated in regulation 6 of these regulations; or

(f) the management and control of the laboratory is not likely to be adequate.

(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 paragraph (2) of regulation 5 of the Private Medical Clinics (Licensing) Regulations, 1995.

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Professional direction, supervision and responsibility for tests.

6. It shall be the duty of every licensee to 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.

Category and types of 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 thereat.

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

Registers and records.

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:

(a) the name and surname, (or initials), Identity Card 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 IX of the Ordinance 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 may be 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 have been 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 of these regulations, as well as all records, shall be retained by the licensee for a period 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.

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10. The licensee shall inform forthwith the Superintendent of Public Health of any infectious disease notifiable under the Prevention of Disease Ordinance, diagnosed at the laboratory, as well as of all pathological samples confirmed for malignancy, with the details of name, address and Identity Card 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) It shall be the duty of the licensee to 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 paragraph (1) of this regulation, 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) It shall be the duty of the licensee to 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) It shall be the duty of the licensee to ensure that the codes referred to in paragraph (3) of this regulation are strictly adhered to by all persons working in the laboratory.

Power of inspection.

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:

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.

Safety and prevention of danger.

13. It shall be the duty of the licensee to 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.

Non-applicability of regulations.

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.

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