

# **GUIDELINES**

under

THE PRIVATE HOSPITALS AND  
MEDICAL CLINICS ACT (1980) AND  
REGULATIONS (1991)

MINISTRY OF HEALTH

SINGAPORE





**GUIDELINES FOR PRIVATE HOSPITALS, MEDICAL CLINICS  
AND CLINICAL LABORATORIES**

under the Private Hospitals and Medical Clinics Act (1980) and  
Private Hospitals and Medical Clinics Regulations (1991)

Issued by Director of Medical Services  
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## Foreword

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The Private Hospitals and Medical Clinics (PHMC) Act and the Regulations under the Act will come into operation on 1 Jan 93.

These Guidelines are to assist the licensee and the management of private hospitals, medical clinics and clinical laboratories in complying with the requirements under the PHMC Act and its Regulations, and other directives that may be issued from time to time by the Director of Medical Services. They cover the application process, general requirements and requirements specific to types of health care establishments.

We hope that these Guidelines will serve as a useful and practical handbook for all health care establishments on the standards required for operating private hospitals, medical clinics and clinical laboratories.

DR KWA SOON BEE  
PERMANENT SECRETARY (HEALTH)/  
DIRECTOR OF MEDICAL SERVICES

January 1993

1 Oct 07

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## Chapter 1 - Introduction

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- 1.1 The Private Hospitals and Medical Clinics Act 1980 and Regulations 1991 regulate and govern the administration and management of all private hospitals, medical clinics and clinical laboratories in Singapore.
- 1.2 All persons who wish to operate a private hospital, a medical clinic or a clinical laboratory must apply for a licence from the Director of Medical Services (hereafter called the Director) and ensure that they comply with the above legislation. It is also their responsibility to keep themselves informed of and to observe all other relevant statutory requirements.
- 1.3 Under the Regulations, it is mandatory for the licensees to comply with any guidelines which are issued from time to time by the Director, such as those published in these Guidelines. These Guidelines describe the minimum standards which must be established and maintained in order to secure licensing from the Director. Any licence issued may also be subject to other terms and conditions as specified by the Director.
- 1.4 Reference to the appropriate Regulation is given in these Guidelines for convenience. Unless otherwise stated, any reference to a medical practitioner shall include a dentist. Unless otherwise stated, private hospitals include nursing and maternity homes.
- 1.5 Licensees and prospective applicants requiring any additional information should contact the Executive Officer, Medical Audit & Accreditation Unit at telephone number 2527546. Copies of the Act and the Regulations are available from the Singapore National Printers.

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## Chapter 2 - Application Forms

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- 2.1 Application for a licence must be made on the Application Form as specified on the First Schedule of the Regulations issued by the Director and submitted with all relevant supporting documents to the Director.
- 2.2 The Application Form shall be typewritten. Where the space provided is insufficient, an applicant may furnish the information on a separate sheet of paper, which shall also be typewritten. Applicants shall ensure that complete and accurate information is given in the Application Form. The Director reserves the right to reject incomplete application forms.
- 2.3 In the Application Form, please note the following:
- a **Name and address of the premises** refer to that of the private hospital, medical clinic or clinical laboratory.
  - b **Date of first establishment** refers to the date when the health care establishment commenced operations.
  - c **Approval from the Planning Department, Ministry of National Development** must be obtained by all private hospitals and clinical laboratories in Singapore before commencement of operations. If applicable, submit a photocopy of the "Notice of Grant of Written Permission" from the Chief Planner, Urban Redevelopment Authority, Ministry of National Development. This section is not applicable to a medical clinic in a Housing Development Board (HDB) estate.
  - d **Clearance from the Singapore Fire Safety Bureau, Ministry of Home Affairs** must be obtained for premises controlled by HDB. Please submit a photocopy of the Approval from the Building Control Department of HDB. For non-HDB premises, submit a photocopy of

either the "Temporary Occupation Licence" or the "Certificate of Statutory Completion" as soon as it is issued by the Public Works Department.

- e The relevant **professional registration number** shall accompany the names of all professionals that are mentioned in the Application Form, for example, the names of doctors shall be accompanied by their Medical Council Registration Number.

2.4 **FORM A** shall be completed by those intending to set up and operate a private hospital, including a maternity or nursing home. For private hospitals with a clinical laboratory, a Quality Assurance Manual for the clinical laboratory must be submitted together with the application. If additional Specialised Services as set out in the Second Schedule of the Regulations are intended subsequent to the application, the licensee must submit an application to the Director together with supporting documents.

2.5 **FORM B** shall be completed by those intending to set up and operate a clinic providing medical and/or dental services. If additional Specialised Services as set out in the Third Schedule of the Regulations are intended subsequent to the application, the licensee must submit an application to the Director together with supporting documents.

2.6 **FORM C** shall be completed by those intending to set up and operate a clinical laboratory. A Quality Assurance Manual must be submitted at the time of application for a licence.

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## Chapter 3 - General Guidelines

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### **Duties and responsibilities of persons who manage a private hospital, medical clinic or clinical laboratory (Regulation 9)**

3.1 Any person who manages a private hospital, medical clinic or clinical laboratory shall, where applicable:

- a at all times exercise close personal supervision of the premises and the persons employed therein and cause all orders and directions of the medical practitioner in charge of the patients to be faithfully and diligently carried out;
- b keep and maintain all materials, equipment and appliances necessary for the proper diagnosis, care or treatment of patients or running of the services and shall provide any additional equipment and appliances as may be directed by the Director from time to time;
- c accept for admission into the private hospital (excluding nursing homes) only those patients recommended by a registered medical practitioner;
- d be responsible for the maintenance of the standards of practice acceptable to the Director;
- e be responsible for the notification for any patient with or suspected to have a notifiable disease, as required under the Infectious Diseases Act.

### **Duty of manager of private hospital (Regulation 10)**

3.2 Further to providing information on the estimated total bill for a period of hospitalisation, private hospitals (excluding nursing and maternity homes) shall also make available to patients prior to admission, comparative information on the average bill size per day at government and private hospitals.

- 3.3 The hospitals are to advise patients using Medisave of the estimated amount of Medisave which can be used.
- 3.4 Where professional fees are charged separately from the hospitalisation charges for the private hospitals, the medical practitioner in charge of the patient shall make available an estimate of the professional fees which are likely to be incurred during his stay.

### **Staff Records**

- 3.5 Every private hospital, medical clinic or clinical laboratory shall keep records of all persons engaged in management or health care services, with the following particulars:
- a name, sex, date of birth, identity card/passport number and address;
  - b qualifications and duties;
  - c date(s) of employment.

### **Cleanliness and Hygiene**

- 3.6 The internal finishes of the premises shall be of such materials which will permit easy washing and cleaning.
- 3.7 Every part of the premises shall be maintained at all times in a clean and sanitary condition and in a good state of repair.

### **Lighting and ventilation**

- 3.8 Adequate lighting and ventilation for the premises shall be provided.

### **Design**

- 3.9 Aids to facilitate the movement of users of the premises (for example, lifts, ramps and handrails) shall be available where appropriate.

**Disposal of infectious and waste materials**

- 3.10 Every private hospital, medical clinic or clinical laboratory shall ensure that all infectious and waste materials shall be properly disinfected and disposed of in accordance with laws such as those administered by the Ministry of Environment and the Ministry of Health, and any other existing laws.

**Guidelines for prevention of transmission of Human Immunodeficiency Virus and other infectious diseases**

- 3.11 Every private hospital, medical clinic or clinical laboratory shall comply with any guidelines that may be issued from time to time by the Director on the prevention of transmission of Human Immunodeficiency Virus and other infectious diseases.

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## **Chapter 4 - Specific Guidelines for Private Hospitals (excluding maternity and nursing homes)**

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### **Medical Records (Regulation 11)**

- 4.1 The particulars which must be included in the patient's registration record shall be the following:
- a patient's name, identity card/birth certificate/passport number, sex, date of birth, ethnic group and residential address;
  - b name and address of the medical practitioner(s) providing the care and treatment or requesting investigations;
  - c dates and times of consultation, admission, investigations, discharge or death.
- 4.2 The medical record of each patient shall include:
- a the admission form;
  - b the patient's medical history, and any referral documents;
  - c clinical findings and progress notes;
  - d medication, nursing care, treatment and diet notes;
  - e record of allergies and other factors requiring special consideration, if any;
  - f reports of all laboratory tests performed;
  - g records of all Xray and other investigations performed;
  - h consent forms, where applicable;
  - i a discharge statement which summarises the significant findings and

events of the patient's stay, condition on discharge and recommendations and arrangements for future care.

- 4.3 Where a surgical procedure has been performed, the following shall also be included:
- a the anaesthetic record, including preoperative assessment;
  - b the operation report, including preoperative and post-operative diagnosis, description of findings, technique used and tissue removed or altered; and
  - c if tissue or body fluid was removed, the histopathology report.
- 4.4 Where there is a maternity service, the following particulars shall also be included:
- a the labour record:
  - b date and time of delivery and whether the result was a livebirth, stillbirth or abortion;
  - c sex, weight and height of the newborn, circumference of head and condition of newborn at birth;
  - d name(s) of person(s) attending to the patient during delivery;
  - e condition of mother and newborn on discharge;
  - f name, address and relationship of the person who received the newborn from the private hospital on discharge.
- 4.5 All medical records shall be accurate, sufficiently detailed, legible, current, secure, complete and confidential and organised to enable:
- a the medical practitioner responsible for the patient to provide continuing care to the patient, to determine later what the patient's condition was at a specific time, and to review the diagnostic and

- therapeutic procedures performed and the patient's response to treatment;
  - b another medical practitioner to render an opinion after an examination of the patient and a review of the medical record;
  - c another medical practitioner to assume the care of the patient at any time;
  - d the retrieval of pertinent information required for utilisation review and quality assurance activities.
- 4.6 All original inpatient and outpatient hospital medical records shall be retained for an appropriate length of time.

### **Facilities**

- 4.7 Patients of different sex shall not be allowed to occupy the same room, except:
- a for patients in an intensive care unit, high dependency area, recovery room or observation room;
  - b for children under twelve years of age, who shall be accommodated in a ward separate from adults;
  - c for newly delivered babies and their mothers.
- 4.8 Every room or ward occupied or intended to be occupied by a patient shall have at least the following:
- a a suitable hospital bed, mattress, a pillow, a chair and a locker facility for every patient;
  - b adequate lighting and ventilation;
  - c bed screening facilities, where necessary;
  - d patient-to-nurse communication system.

- 4.9 There shall be adequate and properly maintained sanitary facilities for patients.
- 4.10 A private hospital with maternity services shall be provided with:
- a Suitable rooms with emergency light and power supply, oxygen and suction facilities and wash basin to be used exclusively as birth rooms; and
  - b Separate milk preparation areas suitably sited and equipped, outside of which no feeds for infants may be prepared.
- 4.11 Bed space provision shall be sufficient:
- a to ensure the comfort and safety of patients;
  - b to prevent disease transmission; and
  - c to allow proper treatment of the patients.

#### **Operation Theatre Facilities (Regulation 15)**

- 4.12 Operation theatre facilities shall be:
- a Large enough to accommodate all personnel, fittings and equipment and to allow all procedures and movements to be carried out in comfort and safety;
  - b Provided with emergency lighting and power supply;
  - c Provided with post-anaesthetic recovery areas with facilities for the delivery of oxygen and negative pressure suction.
- 4.13 Acceptable levels of sterility shall be maintained for the operation theatre, associated facilities and operative equipment.

#### **Intensive Care Unit (Regulation 16)**

- 4.14 The Intensive Care Unit shall be provided with facilities for:
- a the delivery of oxygen and negative pressure suction;
  - b the continuous respiratory and cardiac support of the patient; and
  - c cardiac defibrillation with synchronisation.

### **Transport arrangements**

- 4.15 Every private hospital shall establish arrangements whereby a patient can be transported to other health care establishments for medical treatment.
- 4.16 Where a private hospital intends to provide a service whereby ill persons can be transported, it shall have ambulances which must be appropriately identified, properly equipped and meet all other relevant existing requirements.

### **Linen Service**

- 4.17 Linen shall be:
- a adequately supplied and appropriate to the purposes of the premises;
  - b clean and changed as necessary and at appropriate intervals;
  - c effectively laundered with reasonable precautions taken to prevent its contamination thereafter;
  - d appropriately laundered if it comes into contact with patients with potentially infectious diseases.

### **Blood Services (Regulation 20)**

- 4.18 The Blood Services provided by a private hospital must comply with the relevant guidelines for Specialised Services under Schedules Two and Three.

**Dietetic Services (Regulation 21)**

- 4.19 Persons involved in the preparation and provision of food in private hospitals shall comply with the same requirements as for foodhandlers engaged in the sale of food.
- 4.20 In particular, the following precautions shall be taken:
- a all food handlers shall observe proper personal hygiene and have regular and appropriate health screening;
  - b the food provided shall be properly stored and handled;
  - c food wastes shall be properly disposed in a manner that does not create a nuisance or a breeding place for pests or otherwise permit the transmission of disease;
  - d there must be proper sanitation procedures for cleansing and maintenance of equipment and work areas.
- 4.21 Premises and facilities for preparation and serving of food must similarly meet with all requirements as for premises involved in the sale of food.

**Clinical Laboratory Services (Regulation 23)**

4.22 The Quality Assurance Manual of the laboratory shall be submitted together with the application form for the licence. The format of the Quality Assurance Manual shall include the following:

- a **Philosophy and Objectives** The clinical laboratory shall provide high quality clinical laboratory and diagnostic services. The clinical laboratory is expected to achieve a close and informed relationship with the medical practitioners in respect of the services provided, with particular reference to the easy and rapid access to results, data, opinion and advice.
- b **Organisation, Administration and Records** The clinical laboratory shall have a current written organisational chart, and duties and responsibilities for all classifications of personnel. There shall be effective methods for communication to ensure prompt and reliable reporting. There shall be appropriate record storage and retrieval.
- c **Staffing and Direction** The clinical laboratory shall be directed by a medical practitioner or a scientific staff qualified to assume professional, organisational, and administrative responsibility for the facilities, and for the services rendered. There shall be sufficient personnel who have adequate qualifications and experience to supervise and conduct the work of the laboratories.
- d **Facilities and Equipment** There shall be sufficient space, equipment and supplies within all laboratories to perform the required volume of work professionally and administratively and with accuracy, precision, efficiency and safety.
- e **Policies and Procedures** The clinical laboratory shall have dated, written policies and procedures based upon current knowledge and

principles.

- f **Staff Development & Educational Programmes** There shall be appropriate continuing professional education programmes.
- g **Quality Assurance and Evaluation** There shall be an overall clinical laboratory quality assurance programme which shall include internal and external procedures by which the practice and standards of the clinical laboratory are assessed and by which the reliability and medical usefulness of clinical laboratory data are demonstrated. These procedures shall provide a mechanism to enable the data obtained from the evaluations to be used effectively for the ongoing improvements of the service, in terms of its defined aims and objectives.

4.23 A "trained person" in the Regulations refers to any person who satisfies one of the following requirements:

- a a registered Medical Practitioner who
  - i holds a postgraduate qualification in any pathology subject, including histopathology, cytology, microbiology, immunology, haematology, immunohaematology and biochemistry, OR
  - ii has at least five years of approved experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.
- b A person with a medical degree or a basic degree in a relevant Science subject acceptable to the Ministry of Health Laboratory Board, and five years relevant working experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.
- c A degree in medical laboratory technology acceptable to the Ministry of Health Laboratory Board and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.

- d A pass in the Departmental Qualifying Examinations of the Ministry of Health or a diploma in medical laboratory technology acceptable to the Ministry of Health Laboratory Board and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.
- e Registration as a qualified laboratory technologist in the relevant discipline by the Ministry of Health Laboratory Board based on equivalent qualifications and experience.

#### **Medical Services (Regulation 24)**

4.24 The medical staff shall be properly organised to provide clinical services to patients, to represent the professional needs of the medical staff and to ensure full involvement of the staff in quality control of patient care.

#### **Nursing Services (Regulation 25)**

4.25 The nursing department (or service) shall be directed by an administrator who is a registered nurse with the appropriate qualifications and experience. In the nurse administrator's absence, a registered nurse who is suitably qualified shall be authorised to act in her place.

4.26 The nursing department shall have:

- a A written organisational plan that delineates lines of authority, accountability and communication;
- b Written policies and procedures to guide the provision of nursing care; and
- c Written job descriptions for all categories of nursing staff specifying the functions, responsibilities and specific qualifications of each position.

- 4.27 The hospital nursing department shall be responsible for:
- a The professional conduct and practices of its nurses; and
  - b The nursing care and related duties when nursing students are providing care within a patient care unit.
- 4.28 Nurse staffing shall be such that:
- a The ratio of the nursing staff to patient is not less than 1 to 1.5.
  - b The percentage of Registered Nurses of the total nursing staff as required by this ratio is not less than 60%. The remainder may include enrolled nurses, midwives and nursing aides.
  - c A sufficient number of registered nurses are on duty at all times to give patients the nursing care that requires the judgement and specialised skills of a registered nurse.
- 4.29 In the case of psychiatric and convalescent hospitals, the ratio of nursing staff and health attendants to patients shall not be less than:
- a 1 : 2.5 for acute admission patients, with at least 60% comprising registered nurses;
  - b 1 : 3 for short-stay patients, with at least 60% comprising registered nurses;
  - c 1 : 4 for long-stay, geriatric, rehabilitation and convalescent patients, with at least 40% comprising registered nurses; and
  - d 1 : 5 for mentally retarded and chronic sick patients, with at least 40% comprising registered nurses.
- 4.30 The above guidelines on staffing establishment may be modified in any manner as the Director thinks fit depending on the use of the private hospital.

4.31 Nursing staff organisation shall be such that:

- a Appropriate administration of nursing services is provided on all shifts.
- b A registered nurse is on duty at all times in the ward or unit to plan, supervise and evaluate all nursing care.
- c The patient care assignment is commensurate with the qualifications of each nursing staff, the identified nursing needs of the patient and the prescribed medical regime.
- d A registered nurse is responsible for the safe custody, recording, administration, handling and disposal of controlled drugs.
- e A registered nurse with appropriate specialised skills is on duty at all times where specialised nursing care is required.
- f There is prompt recognition of any untoward change in a patient's condition to facilitate appropriate interventions.

4.32 The nursing department shall maintain high nursing standards, and:

- a Take all reasonable measures to provide optimal quality care.
- b Ensure that the nursing care provided to patients is in accordance with the approved standards of nursing practice.
- c Ensure that a registered nurse assesses each patient's needs and problems within the period established by the nursing department following admission.
- d Have established standards of nursing care and mechanisms for evaluating such care to monitor the quality of nursing care provided.

4.33 The registered nurse shall be responsible for each patient's nursing care plan. The following requirements must be met:

- a The nursing care plans shall be documented in accordance with the

approved standards of nursing practice.

- b The nursing actions shall be carried out according to the care plan and the patient's response shall be recorded.
- c Continuous evaluation of patient shall be performed to determine the patient's current health status.

4.34 The nursing staff shall participate in continuing education to maintain and upgrade their current competency.

4.35 There shall be an ongoing Nursing Quality Assurance Programme to monitor and evaluate the quality and appropriateness of nursing care.

#### **Drugs, etc (Regulation 27)**

4.36 Every private hospital shall maintain:

- a storage of all antiseptics, drugs for external use and disinfectants separate from internal and injectable medication;
- b an adequate supply of medicinal products and appropriate records of such products;
- c a means of identifying the signatures of all medical practitioners authorised to use the pharmaceutical services for prescriptions.

#### **Quality Assurance (Regulation 29)**

4.37 There shall be a Quality Assurance Programme to ensure quality patient care through objective and systematic monitoring, evaluation, identification of problems and action to improve the level and appropriateness of such care.

4.38 The following are essential components of the Quality Assurance Programme.

- a The private hospital shall establish and give full support to a Quality

Assurance Committee, and a hospital-wide quality assurance programme;

- b There shall be a written plan for the Quality Assurance Programme describing its objectives, organisation, mechanisms and scope;
- c The scope of the Quality Assurance Programme shall include a monthly documented review of all deaths, and all tissues removed at operations for disease;
- d The private hospital shall ensure that links are established between the programme, management and the clinical aspects of patient care to ensure that the necessary actions are taken to remedy identified deficiencies.

4.39 The private hospital shall submit to the Director quarterly reports of the findings, recommendations, actions taken and results of actions taken on:

- a avoidable deaths; and
- b tissues removed at operation but reported as normal.

4.40 The private hospital shall ensure that the Quality Assurance Programme is evaluated at least yearly, and revised if necessary.

### **Equipment (Regulation 30)**

4.41 Every private hospital shall ensure that procedures are drawn up regarding the proper use, care and maintenance of all equipment used in the private hospital and shall comply with established or recommended procedures.

4.42 Every piece of equipment used in any endoscopic, operative or invasive procedure shall be rendered sterile by the appropriate procedure.

### **Infection Control (Regulation 31)**

4.43 There shall be an active hospital-wide infection control programme with measures developed to prevent, identify and control infections acquired in or brought into the private hospital. This shall include the following:

- a There is a system for reporting, evaluating and maintaining data on the incidence and trends of infections among patients and personnel;
- b An Infection Control Committee shall be established. Infection Control staff shall be appointed, trained and authorised to carry out such monitoring and control activities;
- c Infection Control activities shall be documented, and pertinent findings communicated to hospital management for follow-up action, and used in the private hospital's education programmes;
- d There shall be written policies, procedures and guidelines for:
  - i aseptic and isolation techniques,
  - ii sanitation procedures,
  - iii prescribing of antibiotics in the hospital;
- e The private hospital shall establish a system:
  - i to detect and alert appropriate authorities about outbreaks of infectious disease among its patients or staff; and
  - ii to prevent and control such an outbreak.
- f The private hospital shall ensure that its infection control policies and procedures are evaluated regularly and on a continuing basis
- g All new employees shall be orientated regarding the programme;

4.44 The Director shall be informed immediately of:

- a Any patient or staff with a notifiable disease,

- b Outbreaks of hospital-acquired infections.

### **Advertising (Regulation 32)**

4.45 The purpose of advertising by a private hospital shall be to inform the public about the types and nature of services which are available. False or misleading statements about the private hospital or other health care establishments or providers are unacceptable and unethical. The advertisements shall conform to the Advertising Standards Association of Singapore (ASAS) Code of Advertising Practices and any guidelines as issued by the Director.

4.46 The information which may be disclosed in advertisements are:

- a General details, including name, address, hours of service, charges, contact person (by designation only);
- b Accommodation facilities, including classes of accommodation, number of beds per class, costs, mode of payment, and facilities attached (for example, bathroom, television, telephone);
- c Professional services (for example, Accident & Emergency, Surgical, Obstetric & Gynaecology, Psychiatry);
- d Special facilities (for example, Ambulance, Coronary Care Unit, Diagnostic Services).

4.47 Mention of the following is prohibited in advertisements:

- a Services which are not owned by the private hospital;
- b Comparison, either direct or by implication, between the services, facilities or employees of one private hospital and another;
- c The use of superlatives in describing the facilities and services of the private hospital and claims of prominence or uniqueness;
- d Any mention of names of doctors or of the personal skills or services of

individual doctors associated with the private hospital;

- e Testimonials of individuals or patients; and
- f Sales promotions.

4.48 Advertising by a private hospital may be in any media in Singapore but shall be restrained, avoiding full page or lengthy advertisements and too frequent advertising.

4.49 All advertisements must be submitted to the Director for approval prior to use.

4.50 Private hospitals which advertise in other countries must comply with all requirements in the countries concerned.

### **Fire precautions (Regulation 33)**

4.51 The precautions against the risk of fire shall include the following aspects:

- a establishing a fire evacuation plan;
- b provision of adequate means of escape in the event of fire and ensuring that all fire escape passages and staircases are clear of obstruction at all times;
- c making adequate arrangements for detecting, containing and extinguishing fire, for the giving of warnings and for the evacuation of all persons in the private hospital in the event of fire;
- d maintenance of fire precautions and fire fighting equipment;
- e making arrangements to secure by means of regular fire drills and practices that all staff in the private hospital and so far as practicable, patients know the procedure to be followed in the case of fire, including the procedure for saving life;
- f conducting fire drills periodically and maintaining a record of all fire

drills; and

- g displaying conspicuously in the premises notices of the procedures to be followed in the event of fire.

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## Chapter 5 - Specific Guidelines for Nursing Homes

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### Medical Records (Regulation 11)

- 5.1 The particulars which must be included in the patient's registration record shall be the following:
- a patient's name, identity card/birth certificate/passport number, sex, date of birth, ethnic group, residential address and contact number of the next of kin;
  - b dates and times of consultation, admission, discharge or death.
- 5.2 The medical record of each patient shall include information on the following:
- a the admission;
  - b the patient's medical condition, and any referral documents;
  - c medication;
  - d nursing care;
  - e progress;
  - f allergies and other factors requiring special consideration, if any.
- 5.3 All medical records shall be accurate, legible, sufficiently detailed, current, secure, complete and confidential and organised to enable:
- a continuity of medical and nursing care to be provided to the patient;
  - b the transfer of medical and nursing care to the appropriate facility when necessary;
  - c any medical practitioner involved in the care of a patient
    - i to provide continuing care to the patient,

- ii to determine later what the patient's condition was at a specific time, and render an opinion after an examination of the patient and a review of the medical record;
- iii to review any investigations and treatment performed and the patient's response to treatment;
- iv to assume the care of the patient at any time.

5.4 All original medical records shall be retained for an appropriate length of time.

### **Facilities**

5.5 Patients of different sex shall not be allowed to occupy the same room.

5.6 Every room or ward occupied or intended to be occupied by a patient shall have at least the following:

- a a suitable bed, mattress, a pillow, a chair and a locker facility for every patient;
- b adequate lighting and ventilation;
- c bed screening facilities, where necessary;
- d an effective system for patient-to-nurse communication.

5.7 There shall be adequate and properly maintained sanitary facilities for patients.

5.8 Bed space provision shall be sufficient:

- a to ensure the comfort and safety of patients;
- b to prevent disease transmission; and
- c to allow proper treatment of the patients.

5.9 A nursing home shall provide:

- a recreational facilities for patients;

- b occupational therapy and physiotherapy for patients, where necessary;  
and
- c counselling services for patients, where necessary.

### **Transport arrangements**

- 5.10 Every nursing home shall establish arrangements whereby a patient can be transported to other health care establishments for medical treatment as necessary.
- 5.11 Where circumstances beyond the control of the nursing home prevent the arrival of a medical practitioner within half an hour of call, these arrangements must be used in a timely manner to transport the ill patient to the relevant health care establishment for treatment.
- 5.12 Where a nursing home intends to provide a service whereby ill persons can be transported, it shall have ambulances which must be appropriately identified, properly equipped and meet all other relevant existing requirements.

### **Linen Service**

- 5.13 Linen shall be:
  - a adequately supplied and appropriate to the purposes of the premises;
  - b clean and changed as necessary and at appropriate intervals;
  - c effectively laundered with reasonable precautions taken to prevent its contamination thereafter;
  - d appropriately laundered if it comes into contact with patients.

### **Dietetic Services (Regulation 21)**

- 5.14 Persons involved in the preparation and provision of food in nursing homes shall comply with the same requirements as for foodhandlers engaged in the sale of food.
- 5.15 In particular, the following precautions shall be taken:
- a all food handlers shall observe proper personal hygiene and have regular and appropriate health screening;
  - b the food provided shall be properly stored and handled;
  - c food wastes shall be properly disposed in a manner that does not create a nuisance or a breeding place for pests or otherwise permit the transmission of disease;
  - d there must be proper sanitation procedures for cleansing and maintenance of equipment and work areas.
- 5.16 Premises and facilities for preparation and serving of food must similarly meet with all requirements as for premises involved in the sale of food.

### **Nursing Services (Regulation 25)**

- 5.17 The nursing department (or service) shall be directed by an administrator who is a registered nurse with the appropriate qualifications and experience. In the nurse administrator's absence, a registered nurse who is suitably qualified shall be authorised to act in her place.
- 5.18 The nursing department shall have:
- a A written organisational plan that delineates lines of authority, accountability and communication;
  - b Written policies and procedures to guide the provision of nursing care;  
and

- c Written job descriptions for all categories of nursing staff specifying the functions, responsibilities and specific qualifications of each position.
- 5.19 The nursing department shall be responsible for the professional conduct and practices of its nurses.
- 5.20 The number and composition of care staff shall be sufficient to provide adequate care to the residents and in accordance to standards set out by the Director. The guidelines on staffing establishment may be modified in any manner as the Director thinks fit depending on the use of the nursing home. There shall preferably be at least one registered nurse contactable at all times.
- 5.21 Nursing staff organisation shall be such that:
- a Appropriate administration of nursing services is provided on all shifts.
  - b The patient care assignment is commensurate with the qualifications of each nursing staff, the identified nursing needs of the patient and the prescribed medical regime.
  - c A registered nurse is responsible for the safe custody, recording, administration, handling and disposal of controlled drugs.
  - d There is prompt recognition of any untoward change in a patient's condition to facilitate appropriate interventions.
- 5.22 The nursing department shall maintain high nursing standards, and:
- a Take all reasonable measures to provide optimal quality care.
  - b Ensure that the nursing care provided to patients is in accordance with the approved standards of nursing practice.
  - c Ensure that a registered nurse assesses each patient's needs and problems within the period established by the nursing department following admission.

- 5.23 The registered nurse shall be responsible for each patient's nursing care plan. The following requirements must be met:
- a The nursing care plans shall be documented in accordance with the approved standards of nursing practice.
  - b The nursing actions shall be carried out according to the care plan and the patient's response shall be recorded.
  - c Continuous evaluation of patient shall be performed to determine the patient's current health status.
- 5.24 The nursing staff shall participate in continuing education to maintain and upgrade their current competency.
- 5.25 There shall be an ongoing quality assurance programme to monitor and evaluate the quality and appropriateness of nursing care.

### **Drugs, etc (Regulation 27)**

- 5.26 Every nursing home shall maintain:
- a storage of all antiseptics, drugs for external use and disinfectants separately from internal and injectable medication;
  - b an adequate supply of medicinal products and appropriate records of such products.

### **Quality Assurance (Regulation 29)**

- 5.27 The Quality Assurance Programme shall include the following activities:
- a infection control review; and
  - b review of deaths, accidents, injuries and patient safety.

- 5.28 The nursing home shall set out standards for the care it provides, to help identify problems and provide opportunities to improve such care.
- 5.29 The findings, recommendations, actions taken and results of actions taken in the Quality Assurance Programme shall be documented and reported to the Director annually.
- 5.30 The Director shall be informed monthly as to the number and individual nature of serious mishaps and accidents occurring among patients.
- 5.31 The nursing home shall ensure that the Quality Assurance Programme is evaluated at least yearly, and revised if necessary.

**Infection Control (Regulation 31)**

- 5.32 Every nursing home shall have written policies, procedures or guidelines for:
  - a aseptic and isolation techniques; and
  - b sanitation procedures.
- 5.33 The nursing home shall establish a system to detect and alert appropriate authorities about outbreaks of infectious disease amongst its patients or staff, and a plan to prevent and control such an outbreak.
- 5.34 The nursing home shall ensure that its infection control policies and procedures are evaluated regularly and on a continuing basis.
- 5.35 All new employees shall be orientated regarding the programme.
- 5.36 The Director shall be informed immediately whenever any patient or staff contracts a notifiable disease.

**Advertising (Regulation 32)**

- 5.37 The purpose of advertising by a nursing home shall be to inform the public about the types and nature of services which they have available. False or misleading statements about the nursing home, other health care establishments or providers are unacceptable and unethical. The advertisements shall conform to the Advertising Standards Association of Singapore (ASAS) Code of Advertising Practices and any guidelines issued by the Director.
- 5.38 The information which may be disclosed in advertisements are:
- a General details, including name, address, hours of service, charges, contact person (by designation only);
  - b Accommodation facilities, including classes of accommodation, number of beds per class, costs, mode of payment, and facilities attached (for example, bathroom, TV, telephone);
  - c Special facilities (for example, ambulance service).
- 5.39 Mention of the following is prohibited in advertisements:
- a Services which are not owned by the nursing home;
  - b Comparison, either direct or by implication, between the services, facilities or employees of one nursing home and another;
  - c The use of superlatives in describing the facilities and services of the nursing home, and claims of prominence or uniqueness;
  - d Any mention of names of doctors or of the personal skills or services of individual doctors associated with the nursing home;
  - e Testimonials of individuals or patients; and
  - f Sales promotions.
- 5.40 Advertising by a nursing home may be in any media but shall be restrained,

avoiding full page or lengthy advertisements and too frequent advertising.

5.41 All advertisements must be submitted to the Director for approval prior to use.

**Fire precautions (Regulation 33)**

5.42 The precautions against the risk of fire shall include:

- a establishing a fire evacuation plan;
- b provision of adequate means of escape in the event of fire and ensuring that all fire escape passages and staircases are clear of obstruction at all times;
- c making adequate arrangements for detecting, containing and extinguishing fire, for the giving of warnings and for the evacuation of all persons in the nursing home in the event of fire;
- d maintenance of fire precautions and fire fighting equipment;
- e making arrangements to secure by means of regular fire drills and practices that all staff in the nursing home and so far as practicable, patients know the procedure to be followed in the case of fire, including the procedure for saving life;
- f conducting fire drills periodically and maintaining a record of all fire drills; and
- g displaying conspicuously in the premises notices of the procedures to be followed in the event of fire.

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## Chapter 6 - Specific Guidelines for Maternity Homes

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### Medical Records (Regulation 11)

- 6.1 The particulars which must be included in the patient's registration record shall be the following:
- a patient's name, identity card/birth certificate/passport number, sex, date of birth, ethnic group, residential address and contact number of next of kin;
  - b name and address of the medical practitioner(s) providing the care and treatment or requesting investigations;
  - c dates and times of consultation, admission, investigations, discharge or death.
- 6.2 The medical record of each patient shall include:
- a the admission form;
  - b the patient's medical history, and any referral documents;
  - c clinical findings;
  - d medication records;
  - e nursing care records, treatment and diet sheets;
  - f progress notes;
  - g record of allergies and other factors requiring special consideration, if any;
  - h reports of laboratory tests performed;
  - i reports of Xray and other investigations performed;

- j consent forms, where applicable;
- k a discharge statement which summarises the significant findings and events of the patient's stay, condition on discharge and recommendations and arrangements for future care.

6.3 The following particulars shall also be included:

- a the labour record;
- b date and time of delivery and whether the result was a live-birth, still-birth or abortion;
- c sex, weight and height of the newborn, circumference of head and condition of newborn at birth;
- d name(s) of person(s) attending to the patient during delivery;
- e condition of mother and newborn on discharge;
- f name and address of the person who received the newborn from the maternity home on discharge.

6.4 All medical records shall be accurate, sufficiently detailed, legible, current, secure, complete and confidential and organised to enable:

- a the medical practitioner responsible for the patient to provide continuing care to the patient, to determine later what the patient's condition was at a specific time, and to review the diagnostic and therapeutic procedures performed and the patient's response to treatment;
- b another medical practitioner to render an opinion after an examination of the patient and a review of the medical record;
- c another medical practitioner to assume the care of the patient at any time;

- d the retrieval of pertinent information required for utilisation review and quality assurance activities.

6.5 All original inpatient and outpatient medical records shall be retained for an appropriate length of time.

### **Facilities**

6.6 Every room or ward occupied or intended to be occupied by a patient shall have at least the following:

- a a suitable hospital bed, mattress, a pillow, a chair and a locker facility for every patient;
- b adequate lighting and ventilation;
- c bed screening facilities, where necessary;
- d patient-to-nurse communication system.

6.7 There shall be adequate and properly maintained sanitary facilities for patients.

6.8 A maternity home shall be provided with:

- a Suitable rooms with emergency light and power supply, oxygen and suction facilities and wash basin to be used exclusively as birth rooms; and
- b Separate milk preparation areas suitably sited and equipped, outside of which no feeds for infants may be prepared.

6.9 Bed space provision shall be sufficient:

- a to ensure the comfort and safety of patients;
- b to prevent disease transmission; and
- c to allow proper treatment of the patients.

### **Transport arrangements**

- 6.10 Every maternity hospital shall establish arrangements whereby a patient can be transported to other health care establishments for medical treatment as necessary.
- 6.11 Where a maternity home intends to provide a service whereby ill persons can be transported, it shall have ambulances which must be appropriately identified, properly equipped and meet all other relevant existing requirements.

### **Linen Service**

- 6.12 Linen shall be:
- a adequately supplied and appropriate to the purposes of the premises;
  - b clean and changed as necessary and at appropriate intervals;
  - c effectively laundered with reasonable precautions taken to prevent its contamination thereafter;
  - d appropriately laundered if it comes into contact with patients.

### **Blood Services (Regulation 20)**

- 6.13 The Blood Services provided by any maternity home must comply with Regulation 20 and the relevant guidelines for Specialised Services under Schedules Two and Three.

### **Dietetic Services (Regulation 21)**

- 6.14 Persons involved in the preparation and provision of food in maternity homes shall comply with the same requirements as for foodhandlers engaged in the

sale of food.

- 6.15 In particular, the following precautions shall be taken:
- a all food handlers shall observe proper personal hygiene and have regular and appropriate health screening;
  - b the food provided shall be properly stored and handled;
  - c food wastes shall be properly disposed in a manner that does not create a nuisance or a breeding place for pests or otherwise permit the transmission of disease;
  - d there must be proper sanitation procedures for cleansing and maintenance of equipment and work areas.
- 6.16 Premises and facilities for preparation and serving of food must similarly meet with all requirements as for premises involved in the sale of food.

### **Nursing Services (Regulation 25)**

- 6.17 The nursing department (or service) shall be directed by an administrator who is a registered nurse with the appropriate qualifications and experience. In the nurse administrator's absence, a registered nurse who is suitably qualified shall be authorised to act in her place.
- 6.18 The nursing department shall have:
- a A written organisational plan that delineates lines of authority, accountability and communication;
  - b Written policies and procedures to guide the provision of nursing care; and
  - c Written job descriptions for all categories of nursing staff specifying the functions, responsibilities and specific qualifications of each position.

- 6.19 The nursing department shall be responsible for the professional conduct and practices of its nurses.
- 6.20 Nurse staffing shall be such that:
- a The ratio of the nursing staff to bed is not less than 1 to 5 patients.
  - b At least 60% of nursing staff are registered midwives, including registered nurses with midwifery qualifications.
  - c There is at least one midwife on duty at all times.
- 6.21 The above guidelines on staffing establishment may be modified in any manner as the Director thinks fit depending on the use of the maternity home.
- 6.22 Nursing staff organisation shall be such that:
- a Appropriate administration of nursing services is provided on all shifts.
  - b The patient care assignment is commensurate with the qualifications of each nursing staff, the identified nursing needs of the patient and the prescribed medical regime.
  - c A registered nurse is responsible for the safe custody, recording, administration, handling and disposal of controlled drugs.
  - d There is prompt recognition of any untoward change in a patient's condition to facilitate appropriate interventions.
- 6.23 The nursing department shall maintain high nursing standards, and:
- a Take all reasonable measures to provide optimal quality care.
  - b Ensure that the nursing care provided to patients is in accordance with the approved standards of nursing practice.
  - c Ensure that a registered nurse assesses each patient's needs and problems within the period established by the nursing department

following admission.

- d Have established standards of nursing care and mechanisms for evaluating such care to monitor the quality of nursing care provided.

6.24 The registered nurse shall be responsible for each patient's nursing care plan. The following requirements must be met:

- a The nursing care plans shall be documented in accordance with the approved standards of nursing practice.
- b The nursing actions shall be carried out according to the care plan and the patient's response shall be recorded.
- c Continuous evaluation of patient shall be performed to determine the patient's current health status.

6.25 The nursing staff shall participate in continuing education to maintain and upgrade their current competency.

6.26 There shall be an ongoing Nursing Quality Assurance Programme to monitor and evaluate the quality and appropriateness of nursing care.

### **Drugs, etc (Regulation 27)**

6.27 Every maternity home shall maintain:

- a storage of all antiseptics, drugs for external use and disinfectants separate from internal and injectable medication;
- b an adequate supply of appropriate medicinal products and appropriate records of such products.

### **Quality Assurance (Regulation 29)**

6.28 There shall be a Quality Assurance Programme which shall include the

following activities:

- a infection control review; and
- b review of deaths, accidents, injuries and patient safety.

6.29 The maternity home shall set out standards for the care it provides, to help identify problems and provide opportunities to improve such care.

6.30 The findings, recommendations, actions taken and results of actions taken in the Quality Assurance Programme shall be documented and reported to the Director annually.

6.31 The Director shall be informed monthly as to the number and individual nature of serious mishaps and accidents occurring among patients.

6.32 The maternity home shall ensure that the Quality Assurance Programme is evaluated at least yearly, and revised if necessary.

### **Equipment (Regulation 30)**

6.33 Every maternity home shall ensure that procedures are drawn up regarding the proper use, care and maintenance of all equipment used in the maternity home and shall comply with established or recommended procedures.

6.34 Every piece of equipment used in any invasive procedure shall be rendered sterile by the appropriate procedure.

### **Infection Control (Regulation 31)**

- 6.35 Every maternity home shall have written policies, procedures or guidelines for:
- a aseptic and isolation techniques; and
  - b sanitation procedures.

- 6.36 The maternity home shall establish a system to detect and alert appropriate authorities about outbreaks of infectious disease amongst its patients or staff, and a plan to prevent and control such an outbreak.
- 6.37 The maternity home shall ensure that its infection control policies and procedures are evaluated regularly and on a continuing basis.
- 6.38 All new employees shall be orientated regarding the programme.
- 6.39 The Director shall be informed immediately whenever any patient or staff contracts a notifiable disease.

### **Advertising (Regulation 32)**

- 6.40 The purpose of advertising by a maternity home shall be to inform the public about the types and nature of services which they have available. False or misleading statements about the maternity home or other health care establishments or providers are unacceptable and unethical. The advertisements shall conform to the Advertising Standards Association of Singapore (ASAS) Code of Advertising Practices and other guidelines issued by the Director.
- 6.41 The information which may be disclosed in advertisements are:
- a General details, including name, address, hours of service, charges, contact person (by designation only);
  - b Accommodation facilities, including classes of accommodation, number of beds per class, costs, mode of payment, and facilities attached (for example, bathroom, TV, telephone);
  - c Special facilities (for example, ambulance service).
- 6.42 Mention of the following is prohibited in advertisements:

- a Services which are not owned by the maternity home;
  - b Comparison, either direct or by implication, between the services, facilities or employees of one maternity home and another;
  - c The use of superlatives in describing the facilities and services of the maternity home and claims of prominence or uniqueness;
  - d Any mention of names of doctors or of the personal skills or services of individual doctors associated with the maternity home;
  - e Testimonials of individuals or patients; and
  - f Sales promotions.
- 6.43 Advertising by a maternity home may be in any media but shall be restrained, avoiding full page or lengthy advertisements and too frequent advertising.
- 6.44 All advertisements must be submitted to the Director for approval prior to use.

**Fire precautions (Regulation 33)**

- 6.45 The precautions against the risk of fire shall include:
- a establishing a fire evacuation plan;
  - b provision of adequate means of escape in the event of fire and ensuring that all fire escape passages and staircases are clear of obstruction at all times;
  - c making adequate arrangements for detecting, containing and extinguishing fire, for the giving of warnings and for the evacuation of all persons in the maternity home in the event of fire;
  - d maintenance of fire precautions and fire fighting equipment;
  - e making arrangements to secure by means of regular fire drills and practices that all staff in the maternity home and so far as practicable,

patients know the procedure to be followed in the case of fire, including the procedure for saving life;

- f conducting fire drills periodically and maintaining a record of all fire drills; and
- g displaying conspicuously in the premises notices of the procedures to be followed in the event of fire.

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## Chapter 7 - Specific Guidelines for Medical Clinics

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### Medical Records (Regulation 11)

- 7.1 Every medical clinic shall maintain a patient's register, clinical notes of consultation, investigation and treatment given.
- 7.2 The particulars to be included in the patient's registration records shall be the following:
- a patient's name, identity card/birth certificate/passport, number, sex, date of birth, ethnic group and residential address;
  - b name and address of the medical practitioner(s) providing the care and treatment;
  - c date and time of consultation.
- 7.3 The medical record of a patient shall include:
- a the registration record;
  - b the patient's medical history, and any referral document;
  - c clinical findings;
  - d prescription record;
  - e treatment record;
  - f record of allergies and other factors requiring special consideration, if any;
  - g reports of all laboratory tests performed;
  - h reports of all Xray and other investigations performed;

- i consent forms, where applicable;
- j where a surgical procedure has been performed,
  - i the anaesthetic record, if any,
  - ii the operative report, including preoperative and postoperative diagnoses, description of findings, technique used and tissue removed or altered, and
  - iii if a specimen is sent for pathological examination, the proper record must be kept including a copy of the pathology report.

7.4 All medical records shall be accurate, sufficiently detailed, legible, current, secure, complete and confidential and organised to enable:

- a the medical practitioner responsible for the patient to provide continuing care to the patient, to determine later what the patient's condition was at a specific time, and to review the diagnostic and therapeutic procedures performed and the patient's response to treatment;
- b another medical practitioner to render an opinion after an examination of the patient and a review of the medical record;
- c another medical practitioner to assume the care of the patient at any time;
- d the retrieval of pertinent information required for utilisation review and quality assurance activities.

7.5 All medical records shall be retained for an appropriate length of time.

### **Resuscitation Facilities (Regulation 39)**

7.6 Every medical clinic shall have:

- a resuscitation facilities for emergencies and adverse reactions to any

form of treatment provided;

- b means to set up an intravenous infusion;
- c means to maintain a clear airway.

7.7 All equipment must be checked at regular intervals to ensure that they are in working order.

7.8 All drugs must be checked to ensure that they have not exceeded expiry dates.

### **Provision of Information on Charges**

7.9 Display of common charges:

Information on the common charges should be prominently displayed within the medical clinic or dental clinic, for example on boards, tent-cards, etc. Supplementary brochures or pamphlets with details of the clinic's charges may also be provided. The charges may be displayed in the form of a fee range and shall include the following types of charges, where applicable:

- a Consultation fees, e.g. long consultation, short consultation, weekend and public holidays consultations, after office hours consultations
- b Vaccination/Immunisation
- c Health screening and Medical reports

7.10 Providing information on additional charges

Patients should be informed of when additional charges will be incurred, for investigation, treatment, procedures etc.

### **Bill Itemization**

7.11 Patients should be informed of every item charged for the clinic visit, e.g. consultation fee, medication (itemized) charges, investigation charge, etc. through itemized billing.

**Option for filling out Prescriptions**

- 7.12 Patients may either fill out their prescriptions at the clinic or to purchase the medicines from any pharmacy of their choice. They must be given prescriptions to purchase the medicines from any pharmacy of their choice, if they request for it.
- 7.13 Patients should be informed of this option, either verbally, or by means of notices clearly displayed in the clinic.

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## **Chapter 8 - Specific Guidelines for Clinical Laboratories**

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### **Licensees of clinical laboratories for general pathological diagnoses (Regulation 44)**

- 8.1 Licence for a clinical laboratory for general pathological diagnoses may be granted to a person who is a registered Medical Practitioner and
- a holds a postgraduate qualification in any pathology subjects including histopathology, cytology, microbiology, immunology, haematology, immunohaematology and biochemistry, OR
  - b has at least five years of approved experience in a clinical laboratory.

### **Licensees of clinical laboratories for limited pathological diagnoses (Regulation 45)**

- 8.2 Applicants may be granted a licence in one or more disciplines based on the qualifications of the applicant:
- a A person with a medical degree or a basic degree in a relevant Science subject acceptable to Ministry of Health Laboratory Board, AND
  - b Five years relevant working experience in a clinical laboratory acceptable to Ministry of Health Laboratory Board.

**Responsibilities of licensees of clinical laboratories (Regulation 46)**

8.3 Every licensee shall ensure that a printed list of the charges for every laboratory test provided is given to the doctor who is a client, for the information of the patient to be tested, or to any person, at his request, who uses the services of the clinical laboratory on his own accord.

**Quality Control (Regulation 48)**

8.4 The Quality Assurance Manual of the laboratory shall be submitted together with the application form for the licence. The format of the Quality Assurance Manual shall be in the following manner:

- a **Philosophy and Objectives** The clinical laboratory shall provide high quality clinical laboratory and diagnostic services. The clinical laboratory is expected to achieve a close and informed relationship with the medical practitioners in respect of the services provided particularly the easy and rapid access to results, data, opinion and advice.
- b **Organisation, Administration and Records** The clinical laboratory shall have a current written organisational chart and job description for all classifications of personnel. There shall be effective methods for communication to ensure prompt and reliable reporting. There shall be appropriate record storage and retrieval.
- c **Staffing and Direction** The clinical laboratory shall be directed by a medical practitioner or a scientific staff qualified to assume professional, organisational, and administrative responsibility for the facilities, and for the services rendered. There shall be sufficient personnel who have adequate qualifications and experience to supervise and conduct the work of the laboratories.
- d **Facilities and Equipment** There shall be sufficient space, equipment

and supplies within all laboratories to perform the required volume of work professionally and administratively and with accuracy, precision, efficiency and safety.

- e **Policies and Procedures** The clinical laboratory shall have dated, written policies and procedures based upon current knowledge and principles.
- f **Staff Development & Educational Programmes** There shall be a continuing professional education programme.
- g **Quality Assurance and Evaluation** There shall be an overall clinical laboratory quality assurance programme which shall include internal and external procedures by which the practice and standards of the clinical laboratory are assessed and by which the reliability and medical usefulness of clinical laboratory data are demonstrated. These procedures shall provide a mechanism to enable the data obtained from the evaluations to be used effectively for the ongoing improvements of the service, in terms of its defined aims and objectives.

#### **Personnel (Regulation 49)**

- 8.5 A "trained person" in the Regulations refers to any person who is qualified in the relevant disciplines as defined in paragraphs 0 and 0 or to one who satisfies one of the following requirements:
  - a A degree in medical laboratory technology acceptable to the Ministry of Health Laboratory Board and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.
  - b A pass in the Departmental Qualifying Examination of the Ministry of Health or a diploma of medical laboratory technology acceptable to the Ministry of Health Laboratory Board and 3 years relevant working

experience in a clinical laboratory acceptable to the Ministry of Health Laboratory Board.

- c Registration as a qualified laboratory technologist in the relevant discipline by the Ministry of Health Laboratory Board based on equivalent qualifications and experience.