

*S1 98/2000*  
*S1 128/2001*

**HOSPITALS AND HEALTH CARE FACILITIES  
 (GENERAL) REGULATIONS, 2000**

(SECTION 30)

*[Commencement 20th December, 2006]*

**PRELIMINARY**

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| Citation       | 1. These regulations may be cited as the Hospitals and Health Care Facilities (General) Regulations, 2000.  |
| Interpretation | 2. In these regulations —   |
| Ch 235         | “Act” means the Hospitals and Health Care Facilities Act, 1998;   |
|                | “anaesthetist “ means a medical practitioner with specialty training in anaesthesiology;  |
|                | “blood bank” means a blood recruitment and transmission facility;   |
|                | “cardiologist” means a medical practitioner with specialty training in diseases of the heart;   |
|                | “cardiology clinic” means a facility where services are provided by a cardiologist;   |
|                | “clinical laboratory” means a facility where tests are performed on individuals to assess their health or determine whether they are diseased;  |
|                | “dental clinic” means a facility where dental services are provided by a dentist;   |
| Ch 226         | “dental hygienist” means a person who is registered and licensed as a dental hygienist under the Dental Act, 1989;  |
| Ch 226         | “dental practitioner” means a person who is registered and licensed as a dental practitioner under the Dental Act, 1989;  |
|                | “diagnostic imaging facility” means a facility where services are provided in intervention imaging, diagnostic x-ray imaging techniques including static radiography and dynamic radiography; |
|                | “dialysis centre” means a facility where artificial renal replacement therapy is performed including haemodialysis or peritoneal dialysis;  |

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- “dynamic radiology “ means radiology studies where physiological information is obtained from the patient and includes fluoroscopy;
- “facility” means a health care facility;
- “haematology and oncology clinic” means a clinic for the treatment of persons suffering from blood diseases and neoplastic diseases or tumors;
- “health professional” means a person who is registered and licensed under the Health Professions Act, 1998; Ch 233
- “health professionals’ office” means a facility where health care services are offered by a health professional registered and licensed under the Health Professions Act, 1998; Ch 233
- “internist” means a medical practitioner who is a specialist in internal medicine;
- “interventional radiology” means radiology that is used in lieu of surgical procedures;
- “laboratory” means a facility where human tissues and fluids are tested;
- “licensee” means the holder of a licence;
- “maternity hospital or birthing centre” means a hospital or other premises in which human babies are delivered;
- “medical laboratory” means a facility that conducts tests in chemistry, haematology, serology, microbiology, cytology or histology or a combination of any of them;
- “medical laboratory technologist” means a person who is registered and licensed as a medical laboratory technologist under the Health Professions Act, 1998; Ch 233
- “medical physicist” means a person who is trained to provide oversight, maintenance and quality control of radiation equipment and to provide radiation protection programs;
- “medical practitioner” means a person who is registered and licensed as a medical practitioner under the Medical Act; Ch 224

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- Ch 233 “medical technician” means a person who is registered and licensed as a medical technician under the Health Professions Act, 1998;
- “megavoltage radiation therapy equipment for external-beam therapy” means a linear accelerator or cobalt-60 teletherapy unit;
- “oral surgeon” means a person who is a dental practitioner with specialty training in oral surgery;
- “pathologist” means a medical practitioner with specialty training in pathology;
- “pathology laboratory facility” means a facility where cytology, surgical pathology and autopsies are performed;
- Ch 233 “pharmacist” means a person who is registered and licensed as a pharmacist under the Health Professions Act, 1998;
- “radiation oncologist” means a medical practitioner who confines his or her professional practice to radiation oncology or therapeutic radiology, who holds a certificate in radiology from the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons in Canada or holds a certification that the Board considers equivalent thereto, or who has completed a residency in radiation oncology or has completed training that the Board considers equivalent thereto;
- “radiation oncology clinic” means a facility that utilizes the energy of ionizing radiation to destroy malignant tissues;
- Ch 233 “radiographer” means a person who is registered and licensed as a radiographer under the Health Professions Act, 1998;
- “radiologist” means a medical practitioner with specialty training in radiology;
- Ch 225 “registered nurse” means a person who is registered under the Nurses and Midwives Act;
- “static radiography” means radiography where morphological information is obtained from the patient;

“surgical centre” means a place where surgical operations are performed under general, local or regional anaesthesia; and

“walk-in clinic” means a medical clinic where no appointment is required to receive medical attention.

**3.** These regulations apply to the following clinics and facilities — Application.

- (a) Blood banks;
- (b) Cardiology clinics;
- (c) Dental clinics;
- (d) Diagnostic imaging facilities;
- (e) Dialysis centres;
- (f) Haematology and oncology clinics;
- (g) Health professionals’ offices;
- (h) Laboratories in medical practitioners’ offices;
- (i) Maternity hospitals or birthing centres;
- (j) Medical laboratories;
- (k) Medical practitioners’ offices;
- (l) Pathology laboratory facilities and clinical laboratory facilities;
- (m) Radiation Oncology clinics;
- (n) Surgical centres, other than surgical centres in a hospital; and
- (o) Walk-in clinics.

**4.** Except where otherwise indicated, every licensee of a health care facility that is licensed as a clinic or facility referred to in section 2 shall ensure that the requirements of Part I of these regulations are met. Obligations of licensee of health care facility.

## PART I GENERAL REQUIREMENTS

**5.** Except where otherwise provided, every clinic and facility — Staff.

- (a) shall be under the direction of a medical practitioner or a person who is licensed under the Health Professions Act, 1998, as the case requires; Ch. 233.

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- (b) shall have on duty during the hours of operation of the clinic or facility a medical practitioner, a person who is licensed under the Health Professions Act, 1998 or a registered nurse with specialty training that relates to the type of clinic or facility being operated; and
- (c) shall have sufficient numbers of qualified staff in the employ of the clinic or facility and sufficient numbers of qualified staff on duty present during the hours of operation of the clinic or facility commensurate with the type of services being offered at the clinic or facility.

Patient records.

**6.** (1) An up to date patient medical record shall be maintained for each patient of a clinic or facility that bears the date each entry is made on the record and includes the following information with respect to the patient —

- (a) name, address and phone number, where available;
- (b) relevant history of illness or injury and physical findings;
- (c) diagnosis;
- (d) a list of all diagnostic tests and procedures carried out by the clinic or facility on the patient together with the date of the tests or procedures, and the results where available;
- (e) clinical observations, including results of treatment;
- (f) allergy history;
- (g) in general and paediatric practices only, growth charts for paediatric patients; and
- (h) referral information.

(2) Patient medical records and reports shall be treated as confidential information and except as provided in paragraphs (3) and (4) and Part XIV, no person shall be allowed to examine a patient's medical record or be given any information, copy or item from a patient's record.

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(3) A health practitioner who is treating a patient may examine the patient's medical record or obtain any information, copy or item from the medical record only for the purpose of providing health care or assisting in the provision of health care to the patient.

(4) Copies from a patient's medical record shall be provided on request to a patient, a personal representative who is authorized by the patient to obtain copies from the record, or if the patient is dead, the patient's legal representative.

(5) Every patient's medical record or a copy of it shall be retained for at least six years following the patient's last visit to the facility or clinic.

7. (1) Every clinic and facility shall be so designed and equipped as to be able to carry out the operations of the clinic or facility in a safe, efficient and effective manner.

Patient care  
setting

(2) Waiting areas and patient registration areas shall be readily accessible to patients, including physically challenged persons, and shall be so constructed and located as to ensure patient privacy and confidentiality without compromising patient care.

(3) Wheelchairs and other ambulating aids as are necessary for patients in the particular circumstances, shall be readily available at the clinic or facility but shall not obstruct entry to any part of the facility or clinic.

(4) Where a clinic or facility may require a patient to provide a specimen, the area for the procurement of specimens shall be in a room that is separate from the room in which patients are examined.

(5) Every clinic and facility shall have an examination room that is properly equipped commensurate with the type of services being offered at the clinic or facility.

(6) Every clinic and facility shall have at least one sink with running water for hand washing that is connected to the drainage system with discharge pipes.

(7) Where a clinic or facility contains a laboratory, the sink referred to in paragraph (6) shall be so constructed as to permit flushing of the eyes, the body and clothes with large quantities of water so as to neutralize any hazardous or corrosive substances in case of an accident.

(8) Every clinic and facility shall have a sufficient number of flush toilets and washrooms to accommodate the volume of patients and employees of the clinic or facility and such toilets and washrooms shall be conveniently located for the patients and employees.

(9) Every clinic and facility shall be lighted with at least sixty watts of lighting and shall be ventilated.

Equipment and  
supplies

8. (1) Every clinic and facility shall establish a preventative maintenance program to ensure that equipment that is required by the manufacturer to be checked or calibrated is done so with a frequency that is in accordance with the manufacturers specifications.

(2) Biological and other supplies requiring refrigeration shall be stored in a refrigerated enclosure and kept separate from food items.

(3) Infectious materials shall be stored in clearly marked containers which prevent leakage during collection, handling, processing, storage, transport, or shipping. The container for storage, transport, or shipping shall be labelled and closed prior to being stored, transported, or shipped. A facility shall treat all human blood and certain human body fluids as if known to be infectious for HIV (human immunodeficiency virus) or HBV (hepatitis B virus). The labelling of specimens is not necessary, provided containers are recognizable as containing specimens. However, labelling is required when such specimen or containers leave the facility.

(4) Flammable liquids in excess of ten gallons shall be contained in a storage cabinet containing not more than sixty gallons that meets the requirements of section 3902 of the Bahamas Building Code.

(5) “No smoking” signs shall be posted at areas in which flammable gases or liquids are stored for use.

(6) Every hospital or health care facility shall contain sufficient storage space for patient records and pharmaceutical supplies.

(7) Approved fire extinguishers in good working order in the number required by the Bahamas Building Code shall be kept on the premises of every clinic and facility.

Patient rights

9. (1) Patients shall be provided with considerate, respectful care at all times and under all circumstances, with due regard to their personal dignity.

(2) No patient shall be denied privacy concerning any matter related to that patient’s medical history.

(3) All patients shall be provided with care that is appropriate in the circumstances.

(4) All patients shall be informed of the identity and professional status of any person providing for the patient’s care.

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(5) The health practitioner that is responsible for coordinating a patient's care shall provide information to the patient with respect to the patient's diagnosis and current prognosis, if known.

**10.** (1) No treatment or procedure shall be performed on a patient without the voluntary, competent and informed consent of the patient or, where the patient is a minor, the consent of the parent or guardian of the patient. Consent

(2) Consent by a patient for a surgical operation shall be made in writing.

(3) Where a patient is unable to give informed consent because the patient is illiterate, physically impaired, mentally impaired, debilitated or incompetent in any way so as not to be able to give informed consent, written consent shall be obtained from a relative or legal representative of the patient prior to the administration of the treatment or procedure on the patient.

(4) Where a patient is unable to give informed consent, and where there is no legal representative or person designated by the patient for this purpose and delay in medical treatment would endanger the life or a limb of the patient, the consent of the patient may be presumed, unless it is obvious from a previous declared expression of the patient that consent would be refused in the situation.

**11.** Every maternity hospital or birthing centre and every surgical centre and dental clinic, shall have written policies and procedures that specify the scope and conduct of the care that they provide, and such policies and procedures shall include at least the following — Policies and procedures

- (a) the mechanism used to inform a patient of the health practitioner responsible for his care;
- (b) the keeping of patient medical records, including a reference to the confidentiality of patient information, the safeguard of medical records, the release of information to authorized individuals and any consent required for treatment of a patient or the administration of any procedure on a patient;
- (c) the scope of treatment and procedures to be performed in patient care areas, including general and specific treatments and procedures that may be performed;



- (d) the mechanism for the provision of care to a minor not accompanied by a parent or guardian;
- (e) the location and storage of medications, supplies and equipment;
- (f) the dispensing of medication in accordance with legal requirements and the responsibility for maintaining the integrity of an emergency drug supply;
- (g) infection control measures;
- (h) the methods used to ensure that the clinic or facility is sanitary and free from nuisance;
- (i) the methods used by the clinic or facility to ensure that the safety and well-being of patients and employees are assured; and
- (j) the mechanism used to report communicable diseases to the Director of Public Health.

Sanitation and  
safety.  
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**12.** (1) The premises of a clinic or facility shall be kept sanitary and free from nuisance in accordance with the Environmental Health Act.

(2) All syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another shall be disposed of as infectious waste in accordance with section 13.

(3) Maternity hospitals, birthing centres, medical laboratories, surgical centres and dental clinics shall ensure that linen, gauze, bandages or any other material that is contaminated with blood or other bodily fluids shall be treated as infectious waste in accordance with section 13.

(4) Any specimen from a patient that is transported abroad for assessment, shall be shipped in accordance with shipping guidelines as set out in IATA regulation 650.

Infectious waste  
and radioactive  
waste.

- 13.** (1) Infectious waste shall —
- (a) be stored in double impervious plastic bags that are —
    - (i) securely fastened;
    - (ii) conspicuously marked “infectious waste”; and
    - (iii) when full do not exceed twenty-five pounds in weight;

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- (b) be transported in receptacles that are conspicuously marked “infectious waste”;
  - (c) be incinerated or otherwise processed to render the waste harmless or shall be held for pick-up in specially marked non-metal containers separate from regular waste;
  - (d) be secured from unauthorized persons;
  - (e) be secured from birds and animals;
  - (f) not be removed by mechanical means or compacted; and
  - (g) not be deposited in any landfill.
- (2) Broken or leaking bags of infectious waste shall not be permitted to be transported from a clinic or facility unless it is re-bagged in accordance with this section.
- (3) Where trash that may constitute a hazard to any person or thing is compacted and the integrity of the container is compromised, that container shall be handled as infectious waste under this section.
- (4) Radioactive waste shall be stored in specially marked radioactive waste containers, or in separate rooms. Waste containing radioactive material with short half lives shall be stored until it decays to background radiation levels for ultimate disposal with non-radioactive medical waste. Waste containing longer-lived radioactive material shall be stored or sent to a radioactive waste disposal facility. Radioactive storage areas shall be posted to identify the radioactive waste so that workers and the public will not inadvertently enter the areas.

## PART II BLOOD BANKS

**14.** Every licensee of a health care facility that is licensed as a blood bank shall ensure that the requirements of this Part are met. Blood Banks

**15.** Every blood bank shall be under the direction of a medical practitioner or a pathologist. Staff

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**PART III  
CARDIOLOGY CLINICS**

Cardiology  
clinics.

**16.** Every licensee of a health care facility that is licensed as a cardiology clinic shall ensure that the requirements of this Part are met.

Cardiology staff.

- 17.** Every cardiology clinic shall —
- (a) be under the direction of a physician who is an internist or a paediatrician with advanced training in cardiology from an institution approved by the Board; and
  - (b) have on staff a medical practitioner or a registered nurse with specialty training approved by the Board.

**PART IV  
DENTAL CLINICS**

Dental clinics.

**18.** Every licensee of a health care facility that is licensed as a dental clinic shall ensure that the requirements of this Part are met.

Dental staff.

- 19.** (1) Every dental clinic —
- (a) shall be under the direction of a dental practitioner; and
  - (b) shall have on staff a dental hygienist.
- (2) Every dental clinic where oral surgery or maxillo-facial surgery is carried out, and where general, intravenous or any other type of regional anaesthesia is being administered, shall have on staff, an anaesthetist or a dental practitioner with specialty training in anaesthesiology.

Policies and  
procedures.

**20.** Every dental clinic where oral surgery or maxillo-facial surgery is carried out shall, except where otherwise provided, meet the requirements of Part XIII.

**PART V  
DIAGNOSTIC FACILITIES**

Diagnostic  
imaging facilities.

**21.** Every licensee of a health care facility that is licensed as a diagnostic imaging facility shall ensure that the requirements of this Part are met.

**22.** (1) Every diagnostic imaging facility shall have written policies and procedures for monitoring and evaluating the effective management, safety and operation of imaging equipment so as to minimize patient, personnel and public radiation risks and maximize the quality of the diagnostic information.

Policies and procedures relating to diagnostic imaging facilities

(2) The premises of every clinic or facility that has an x-ray department, shall conform to standard structural requirements for protection from radiation as set out in American College of Radiology Standards.

(3) Waiting areas and change rooms shall be so situated as to prevent exposure to radiation.

(4) Equipment performance shall be monitored and machine calibration shall be checked by a medical physicist at least twice a year or in accordance with the manufacturer's specifications, and records of such monitoring and calibration shall be kept in the clinic or facility and shall be readily available upon the request of an inspector.

(5) Machines requiring calibration shall be calibrated as soon as is practicable.

(6) Images shall be clearly labelled with the examination date, patient identification and image orientation and a written report of the image results shall be included with the patient's medical record.

(7) Every diagnostic imaging facility that is a stand alone clinic shall be under the direction of a radiologist.

(8) X-rays shall be taken by a radiographer or by staff with such training in radiology as the Board deems appropriate.

## PART VI DIALYSIS CLINICS

**23.** Every licensee of a health care facility that is licensed as a dialysis clinic shall ensure that the requirements of this Part are met.

Dialysis clinics

**24.** (1) Every facility licensed as a dialysis clinic shall be under the direct supervision of a nephrologist or internist with specialty training from an institution approved by the Board.

Dialysis staff

(2) The staff to patient ratio at the dialysis clinic shall be a minimum of one dialysis trained health practitioner for every three patients.

Policies and procedures.

**25.** (1) Every facility providing haemodialysis services to patients shall have written policies and procedures for maintaining, monitoring and evaluating the effective management, safety and operation of equipment in the facility and of services provided in the facility.

(2) The policies and procedures referred to in paragraph (1) shall be so designed as to minimize patient, personnel and public risks and to maximize the quality of haemodialysis care.

Nursing station.

**26.** Every dialysis clinic shall have a central nursing station with a clear view of the entire treatment area such that all patients are in line of sight of the nursing staff.

Dialysis treatment.

**27.** (1) There shall be an adequate number of sinks for implementing precautions relating to infection control.

(2) Walls and floors shall be smooth and washable so that decontamination procedures can be carried out easily.

(3) Every dialysis clinic shall ensure that in addition to the dialysis treatment area the following areas in the clinic are clearly defined —

- (a) clean-up area;
- (b) clean supply room;
- (c) equipment storage;
- (d) water treatment area;
- (e) lockers and bathrooms for patients and staff;
- (f) general reception area; and
- (g) waiting room for patients and visitors.

Infection control.

**28.** Used blood lines and dialysers shall be treated as infectious waste in accordance with section 13.

Water control.

**29.** The quality of the water used in the dilution of the dialysis concentrate shall be in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) water treatment equipment and quality recommendations for haemodialysis.

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**PART VII**  
**HAEMATOLOGY AND ONCOLOGY**  
**CLINICS**

**30.** Every licensee of a health care facility that is licensed as a haematology and oncology clinic shall ensure that the requirements of this Part are met.

Haematology and oncology clinics.

**31.** (1) A clinic that is licensed as a haematology and oncology clinic shall be under the direction of a medical practitioner with specialty training in oncology.

Haematology and oncology staff.

(2) A clinic in which medical oncology is provided, shall be under the direction of a medical practitioner with specialty training in medical oncology and shall also have on staff, registered nurses with specialty training in medical oncology.

(3) A clinic that is licensed as a haematology and oncology clinic shall have on duty during the hours of operation, at least one member of staff who is a medical practitioner with specialty training in oncology or a registered nurse with special training in oncology.

**32.** (1) Only persons referred by a medical practitioner shall be accepted into care at a haematology and oncology clinic.

Referral to clinic.

(2) The clinic shall ensure that the referring medical practitioner submits the reason for the referral and that the referral is accompanied by slides of tissue specimen where necessary to properly treat the patient.

(3) Where a patient is accepted as a patient in a haematology and oncology clinic, the Administrator shall inform the patient of the practitioner responsible for his care.

**33.** (1) Tissue that is removed from a patient in a haematology and oncology clinic shall be sent to a pathologist for examination and any malignancy reported to the Cancer Registry of the Princess Margaret Hospital.

Tissue to clinic.

(2) Every haematology and oncology clinic shall be linked to the Cancer Registry of the Princess Margaret Hospital so that the treatment protocol can be reviewed and monitored by the Hospital's Tumour Board.

Administration  
of chemo-  
therapeutic  
agents.

**34.** (1) Every clinic in which chemotherapy is administered shall have written policies and procedures with respect to the preparation of drugs to ensure the safety of staff and patients.

(2) Every clinic in which chemotherapy is administered shall have a pharmacy preparation room.

(3) Specimen preparation shall only be carried out by a pharmacist or registered nurse who has specialty training in oncology and in the administration of chemotherapy drugs.

(4) Every clinic in which chemotherapy is administered shall have written policies and procedures for the management of adverse effects of such treatment on patients.

(5) Every clinic in which chemotherapy is administered shall obtain written consent from the patient or the patient's legal representative before administering chemotherapy drugs.

(6) Where a patient will be receiving chemotherapy drugs at home, the clinic shall provide instructions to the patient or, where applicable in the circumstances, to any other person who will be assisting the patient or administering the drugs to the patient.

### PART VIII MEDICAL PRACTITIONERS' LABORATORIES

Laboratories in  
medical  
practitioner's  
offices.

**35.** Every licensee of a health care facility that is licensed as a medical practitioner's office and that is also licensed to operate a laboratory in the medical practitioners' office shall ensure that the requirements of this Part are met.

Scope of tests to  
be formed.

**36.** (1) A laboratory may only perform the following tests —

- (a) haematology;
- (b) microbiology;
- (c) clinical chemistry; and
- (d) immunology.

(2) A laboratory may only perform a test on a patient at the written request of a medical practitioner or, where permitted under the Health Professions Act, 1998, by a

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person registered and licensed under that Act, or by staff with such training in medical laboratory technology as the Board deems appropriate.

(3) The results of a test on a patient shall only be sent to the health professional ordering the test.

**37.** The laboratory shall have a quality control program approved by the Board that covers all the types of analyses performed by the laboratory.

Quality control.

## **PART IX MATERNITY HOSPITAL**

**38.** Every licensee of a health care facility that is licensed as a maternity hospital or birthing clinic shall ensure that the requirements of this Part are met.

Maternity hospital or birthing centres.

**39.** (1) Every maternity hospital or birthing centre shall be under the direction of a medical practitioner who holds specialist qualifications in obstetrics.

Maternity Staff.

(2) Every maternity hospital or birthing centre shall have on staff at all times, at least one midwife for every two patients.

**40.** (1) A patient in labour shall be managed by a midwife under the direct supervision of the physician who is responsible for the patient's care.

Competent staff-maternity.

(2) Where the physician referred to in paragraph (1) is not specially trained in obstetrics, the facility shall have an established written agreement with an obstetrician or gynaecologist to provide twenty-four hours direct consulting access for the physician referred to in paragraph (1).

**41.** Every maternity hospital or birthing centre shall have and maintain at all times —

Accommodation.

- (a) a delivery room;
- (b) operable refrigeration and bottle sterilization facilities; and
- (c) operable resuscitation equipment including a supply of oxygen and suction apparatus commensurate with the number of patients in the facility.



Surgical  
operations

**42.** Every maternity hospital or birthing centre in which surgical operations are performed shall meet the requirements of Part XIII.

Reporting of  
deaths

**43.** Every death which occurs in a maternity hospital or birthing centre shall be reported to the Director of Public Health.

## PART X GENERAL MEDICAL LABORATORIES

Medical  
Laboratories

**44.** Every licensee of a health care facility that is licensed as a medical laboratory shall ensure that the requirements of this Part are met.

Staff

**45.** (1) Every medical laboratory shall be under the direction of a person registered and licensed under the Health Professions Act, 1998.

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(2) Every medical laboratory shall have on staff medical technicians who are qualified to perform the procedures undertaken by the laboratory.

(3) At least one medical laboratory technologist shall be available on the premises of a medical laboratory during all hours when laboratory tests are performed.

Scope of service

**46.** Every medical laboratory shall post a list of all tests that are carried out by the facility and those tests that are carried out by another facility on behalf of the laboratory.

Collection  
stations

**47.** (1) The collection of specimens shall only be performed under the general supervision of a medical practitioner, the laboratory director, the supervisor or a medical laboratory technologist.

(2) Every medical laboratory shall post in a conspicuous place in the laboratory, written instructions for the handling, preservation, storage and transportation of specimens.

Records

**48.** (1) Every medical laboratory shall keep records and reports of all tests undertaken at the facility and those that are carried out by another facility on behalf of the laboratory.

(2) All records and reports of tests performed, including reports received from another laboratory, shall be kept on the premises of the requesting laboratory and the laboratory that performed the tests, for a period of seven years.

(3) Records and reports referred to in this regulation may be kept in electronic form provided they can be reproduced in readable form.

(4) Records and reports referred to in this regulation shall be made available to an inspector upon request.

**49.** (1) Every medical laboratory shall report to the Director of Public Health without any patient identifier, those tests that a medical practitioner is required to report under the Health Services Act.

Reportable  
diseases.

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(2) A medical laboratory reporting under paragraph (1) shall ensure the confidentiality of all information reported.

**50.** (1) Fume hoods that safely vent toxic and volatile vapours to the outside shall be installed wherever toxic and volatile chemicals are used.

Accommodation.

(2) Fire blankets with instructions for proper use shall be kept on the premises of every medical laboratory.

(3) Written fire control and evacuation plans together with clearly marked fire escape routes shall be posted in a conspicuous place in every medical laboratory.

(4) Every medical laboratory shall have emergency power available during a power failure to provide for refrigeration of those things required to be refrigerated under this regulation and to supply heat, if required in the circumstances.

## PART XI PATHOLOGY FACILITIES

**51.** Every licensee of a health care facility that is licensed as a pathology and clinical laboratory facility shall ensure that the requirements of this Part are met.

Pathology and  
clinical  
laboratory  
facilities.

**52.** Every pathology and clinical laboratory facility shall designate an area for the procurement and storage of specimens and infectious waste.

Accommodation.

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Tracings.

**53.** Abnormal ECG tracings shall be confirmed by an internist or a cardiologist.

**PART XII  
RADIATION ONCOLOGY CLINICS**

Radiation oncology clinics.

**54.** Every licensee of a health care facility that is licensed as a radiation oncology clinic shall ensure that the requirements of this Part are met.

Staff.

- 55.** Every radiation oncology clinic —
- (a) shall be under the direction of a radiation oncologist;
  - (b) shall have on staff medical physicists and support personnel at the levels that follow the guidelines set forth in the 1999 version of the report of the Intersociety Council for Radiation Oncology;
  - (c) shall have on staff for the care of patients, nurses with experience in the care of radiation therapy patients; and
  - (d) shall have on staff a medical physicist responsible for supervising the quality management program of the clinic and for documenting the maintenance and repair of equipment.

Policies and guidelines.

- 56.** Every radiation oncology clinic —
- (a) shall have written policies and guidelines for equipment utilization that provide for maintenance and repair at such intervals as to ensure safe operation and use of the equipment at the clinic; and
  - (b) shall have a written program with respect to quality management covering all treatment modalities offered at the clinic.

Equipment.

- 57.** (1) Every radiation oncology clinic shall be equipped with the following equipment which shall be in good working order —
- (a) megavoltage radiation therapy equipment for external-beam therapy;
  - (b) electron beam or x-ray equipment for the treatment of skin lesions;

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- (c) a simulator capable of duplicating the setups of any megavoltage unit and producing radiographs of the fields to be treated;
  - (d) where brachytherapy is used at the clinic, brachytherapy equipment appropriate for intracavitary and interstitial treatment;
  - (e) a treatment planning computer capable of providing external-beam and brachytherapy dose distribution;
  - (f) physics calibration devices for all equipment;
  - (g) beam-shaping devices;
  - (h) immobilization devices; and
  - (i) radiation survey meters.

(2) Where the megavoltage radiation therapy equipment for external-beam therapy referred to in paragraph (a) of paragraph (1) is a cobalt-sixty unit, the equipment shall have a treatment distance of eighty centimetres or more.

(3) A radiation oncology clinic that has an agreement with another clinic or facility for use of brachytherapy equipment for intracavitary and interstitial treatment is exempt from the requirement of paragraph (d) of paragraph (1).

**58.** (1) Every radiation oncology clinic shall have patient protection measures that include —

Patient and  
personnel safety

- (a) charting systems for prescription, definition and delivery of treatment parameters, and daily dose recording and summation, including forms appropriate for brachytherapy procedures;
- (b) a physics program for calibration of equipment that ensures accurate dose delivery to the patient, including external beam and brachytherapy;
- (c) a system for having a person other than the person treating the patient check the initial dose calculation before the third fraction or 20% of total dose is given to the patient where the treatment schedule is less than 10 fractions;
- (d) a system for having a person other than the person treating the patient check the weekly doses delivered as treatment progresses;

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- (e) a system for having a person other than the person treating the patient check the initial dose for single or two-fraction treatments before any treatment is given;
  - (f) where brachytherapy is used at the clinic, a system to ensure that the radiation oncologist and medical physicist each check all brachytherapy parameters to be used in each procedure;
  - (g) a program to ensure that the patient is protected from mechanical injury by any machine or accessory equipment in the clinic; and
  - (h) visual and audio contact with the patient while the patient is under treatment.
- (2) Every radiation oncology clinic shall have personnel safety measures that include —
- (a) a radiation exposure monitoring program as set out in the Nuclear Regulatory Commission guidelines;
  - (b) inspections of interlock systems as set out in the Nuclear Regulatory Commission guidelines;
  - (c) room shielding as set out in the Nuclear Regulatory Commission guidelines;
  - (d) routine leak testing of all sealed sources as set out in the Nuclear Regulatory Commission guidelines;
  - (e) safety equipment for use of sealed sources as set out in the Nuclear Regulatory Commission guidelines; and
  - (f) quarterly inventory of all radioactive materials.

### PART XIII SURGICAL FACILITIES

Surgical centres

**59.** Every licensee of a health care facility that is licensed as a surgical centre shall ensure that the requirements of this Part are met.

Staff

**60.** Except for dental clinics, every surgical centre where general intravenous or any other type of regional anaesthesia is being administered shall have an anaesthetist on staff.

**61.** (1) Where surgical procedures are provided in an ambulatory care setting, the surgical centre shall have policies and procedures that are consistent with those applicable to inpatient surgery, anaesthesia, and post-operative recovery.

Policies and  
procedures

(2) The policies and procedures referred to in paragraph (1) shall include —

- (a) the types of elective operative procedures that may be performed in the centre and the locations where they may be performed;
- (b) the scope of anaesthesia services that may be performed in the centre and the locations where such anaesthesia services may be administered;
- (c) the available pre-operative and postoperative transportation; and
- (d) the available postoperative care, including post anaesthesia recovery.

(3) Every patient in a surgical centre who receives anaesthesia, other than local anaesthesia, shall be examined before discharge and shall be accompanied home by a person designated by the patient.

(4) The examination referred to in paragraph (3) shall be performed by a medical practitioner or an oral surgeon, as the case requires.

(5) When a patient is discharged from a surgical centre, the centre shall provide written instructions for follow-up care to the patient or other person providing care to the patient including directions for obtaining an appropriate medical practitioner or oral surgeon for postoperative problems.

**62.** (1) Before a patient is submitted to any anaesthetic or undergoes any surgical operation, the patient's history, the results of any physical examination and a written pre-operative diagnosis shall be recorded in the patient's record by the operating surgeon or any medical practitioner so authorized by the surgeon.

Patient's history  
to be recorded

(2) Where in the opinion of the operating surgeon, compliance with paragraph (1) would result in delay detrimental to the patient, the surgeon shall so state in writing and shall record and sign only the pre-operative diagnosis.

Description of operation in patient's medical record.

**63.** Every operation performed in a surgical centre shall be concisely described in writing by the operating surgeon or his assistant and such written description shall form part of the patient's medical record.

Operation register.

**64.** Every surgical centre shall keep an operations register showing the name of the patient, the date and nature of the operation, the name of the surgeon, the name of the anaesthetist, the anaesthetic given and the time the operation began and was completed.

Anaesthetist.

**65.** The anaesthetist shall furnish to the surgical centre, a record showing the type of anaesthetic given, the amount used, the length of time the anaesthetic was administered to the patient and the condition of the patient following the operation.

Surgical procedures.

**66.** An accurate and complete description of the techniques and findings of every operative procedure performed at a surgical centre shall be dictated or written immediately following surgery by the surgeon who performed the operation.

Removal of tissues.

**67.** (1) Any tissue removed during an operation shall be set aside, preserved and labelled by the operating surgeon.

(2) After the tissue is set aside under paragraph (1), the Administrator shall forward the tissue together with a short history of the case and a statement of the findings at the operation to a laboratory approved by the Board to be grossly examined, evaluated by and reported upon by a pathologist.

(3) The pathological report received by the surgical centre from the laboratory shall become part of the patient's medical record.

## PART XIV INSPECTORS

Qualifications of inspectors.

**68.** An inspector appointed under section 25 of the Act shall be required to hold a Diploma in an Allied Health Profession or a First Degree in Medicine or such other speciality qualification as the Board may approve.

**69.** (1) Except as provided in paragraph (2), an inspector may, on the production of his or her appointment, enter at any reasonable time a clinic or facility to be inspected and inquire into and examine the clinic or facility, including any book or record of the clinic or facility that is required to be kept under this regulation.

Powers and  
duties of  
inspectors

(2) An inspector referred to in paragraph (1) may only inquire into and examine a patient record at a clinic or facility if the inspector is a medical practitioner, or where the premises being inspected is a dental clinic, a dentist, and the inspector has been appointed by the Board to do so.

(3) The Board may only appoint an inspector to inquire into and examine a patient record at a clinic or facility if —

- (a) the Board has received a complaint with respect to a patient record at the clinic or facility;
- (b) the Board has received a complaint with respect to a matter under this regulation that relates to a patient record at the clinic or facility; or
- (c) the Board has reason to believe that regulation 6 has not been complied with or that another paragraph of this regulation has not been complied with and that compliance can only be determined by inspecting a patient's record at the clinic or facility.

(4) No person shall obstruct an inspector or withhold or conceal from the inspector or destroy anything that is relevant to the inspection.

(5) A magistrate may, on the application of an inspector, issue a warrant authorizing an inspector to enter and search a place and examine anything that is relevant to the inspection if the magistrate is satisfied that the inspector has been properly appointed and that there are reasonable and probable grounds for believing that there is something relevant to the inspection at the place.

(6) A warrant issued under paragraph (5) does not authorize an entry or search after sunset and before sunrise unless it is expressly stated in the warrant.

(7) An inspector entering and searching under the authority of a warrant issued under paragraph (5) may be assisted by other persons and may enter a place by force.



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(8) An inspector entering and searching a place under the authority of a warrant issued under paragraph (5) shall produce his or her identification, on request, to any person at the place.

(9) An inspector may copy, at the expense of the clinic or facility, a document or an object that an inspector may examine under this regulation or under the authority of a warrant issued under paragraph (5).

(10) An inspector may remove a document or object described in paragraph (1) or paragraph (9) if —

- (a) it is not practicable to copy it in the place where it is examined; or
- (b) a copy of it is not sufficient for the purposes of the investigation.

(11) If it is practicable to copy a document or object removed under paragraph (10), the inspector shall —

- (a) if it was removed under paragraph (10)(a), return the document or object within a reasonable time; or
- (b) if it was removed under paragraph (10)(b), provide the person who was in possession of the document or object with a copy of it within a reasonable time.

(12) A copy of a document or object certified by an inspector to be a true copy shall be received in evidence in any proceeding to the same extent and shall have the same evidentiary value as the document or object itself.

(13) In this regulation, “document” means a record of information in any form and includes any part of it.

(14) An inspector shall only report the results of an inspection to the Board.

(15) Except as provided under paragraph (16), an inspector acting under this regulation and the Board shall not disclose, to any person any information reported to the Board.

(16) The results of a report to the Board may, with the concurrence of the Board, be disclosed to a committee of the Board for the purpose of showing that the holder of a licence for a clinic or facility knowingly gave false information.