GUYANA No. 7 of 2008

REGULATIONS

Made Under

THE HEALTH FACILITIES LICENSING ACT 2007

(ACT NO. 26 OF 2007)

IN EXERCISE OF THE POWERS CONFERRED UPON ME BY SECTION 29 READ WITH SECTION 2 OF THE HEALTH FACILITIES LICENSING ACT 2007, I MAKE THE FOLLOWING REGULATIONS:-

PART I

PRELIMINARY

Citation and commencement.

1. (1) These Regulations may be cited as the Health Facilities Licensing Regulations 2008.

(2) These Regulations shall come into force on the 1st day of May 2008.

Interpretation.

2. In these Regulations-

"anesthesiologist" means a medical practitioner with specialty training in anesthesiology qualified to practice as an anesthesiologist;

"blood bank" means a blood recruitment, transmission and storage facility;

"cardiologist" means a medical practitioner who is an internist with specialty training in the diseases of the heart qualified to practice as a cardiologist;

"clinical laboratory" means a facility where clinical tests, other than tests performed by a medical laboratory, are performed on individuals;

"community health worker" means a person who is selected by a community to

provide basic health care in the community, and who has completed a community health worker programme approved by the Minister;

"diagnostic imaging facility" means a facility where services are provided in interventional radiology, ultrasound, diagnostic X-ray imaging service techniques including static radiography, dynamic radiography, computerized tomography, magnetic resonance imaging, positron emission tomography or other similar devices;

"diagnostic radiographer" means a person who is trained as a diagnostic radiographer to a standard acceptable to the Minister;

"dialysis centre" or "dialysis clinic" means a health facility centre where artificial renal replacement therapy including haemo-dialysis or peritoneal dialysis is performed;

"health centre" means a health facility that provides primary health care and ordinarily working at least from Monday to Friday with a part – time or full – time Medex or community health worker, where in –patient services are limited to over – night stays to stabilize or observe a patient and, if a nurse or midwife is present, to perform routine health care deliveries;

"hospital" means a facility that provides on a daily basis, medical consultations, laboratory and diagnostic radiology services, scheduled and non-scheduled out – patient and in – patient care for stay not exceeding fourteen days and medical nursing services;

"human tissue bank" means a supply of human tissue that is used in aid of or in lieu of surgical procedures;

"licensed" means licensed under the Act;

" licensee" means the holder of a license issued under the Act;

"maternity ward" means a ward or area earmarked in a hospital or health centre where human babies are delivered;

Act 19 of 1978.

"medex" means a person who is registered as a medex under the Medex Act 1978;

Act 16 of 1991.

"Medical Council" means the Medical Council of Guyana established by section 3 of the Medical Practitioners Act 1991;

"medical laboratory" means a health facility for the examination and testing of materials or fluids derived from human body for the purposes of providing information on the diagnosis, prevention or treatment of diseases;

"medical physicist" means a person who is trained to provide oversight, maintenance and quality control of radiation equipment and to provide radiation

protection programmes;

"medical laboratory technologist" means a person who is trained as a medical laboratory technologist to a standard acceptable to the Minister;

"medical practitioner" means a person qualified to practice medicine or surgery and who is duly registered as a medical practitioner under the Medical Practitioners Act 1991 and whose name appears in the register of the Medical Council;

Act 16 of 1991.

"midwife" means a person who is registered as a midwife under the Nurses and Midwives Registration Ordinance;

Cap.137 (o)

"nephrologists" means a medical practitioner who is an internist with specialty training in nephrology and who is registered with the Medical Council as a nephrologists;

"nurse" means a person who is registered as a nurse under the Nurses and Midwives Registration Ordinance;

Cap.137 (o)

"nurse anesthetist" means a nurse with specialty training in anesthesiology;

"nurse assistant" means a person who has completed a nurse assistant training programme approved by the Minister;

"oncology clinic" means a clinic for the treatment of persons suffering from neoplastic diseases or tumors;

"out – patient clinic" means a healthy facility where diagnosis, treatment, ambulatory care, or health information, or any combination thereof is provided;

"pathologist" means a medical practitioner with specialty in pathology and qualified to practice as a pathologist;

"pathology laboratory" means a facility where cytology, surgical pathology and autopsies are performed;

"pharmacist" means a person who is registered as a pharmacist under the Pharmacy Practitioners Act, 2003;

Act 9 of 2003.

"radiologist" means a medical practitioner with specialty training in radiology and qualified to practice as a radiologist;

"regional health authority" means a regional health authority established under the

Act 4 of 2005.

Regional Health Authorities Act 2005;

"registered nurse" means a person who is registered as a nurse under the Nurses and Midwives Registration Ordinance;

Cap.137 (o)

"static radiography" means radiography where morphological information is obtained from the patient;

"surgical centre" means a place where surgery is performed under general, local or regional anesthesia.

Health facilities prescribed.

3. These Regulations apply to the following health facilities which are prescribed as health facilities under section 2 of the Act:-

(a) Blood Banks;
(b) Diagnostic Imaging Facilities;
(c) Dialysis Centres or Dialysis Clinic;
(d) Health Centres;
(e) Hospitals;
(f) Human Tissue Banks;
(g) Maternity Wards;
(h) Medical Laboratories;
(i) Nursing Homes;
(j) Oncology Clinics with Radiation Therapy;
(k) Pathology and Clinical Laboratory; and
(l) Surgical Centres.

Obligations of licensee of the health facilities.

4. (1) Except as otherwise provided, every licensee of a health facility that is licensed as a health facility referred to in regulation 3 shall ensure that the requirements of Part II of these Regulations are met.

(2) Every person who operates a health facility prescribed in these Regulations on the commencement of the Act and required to obtain a licence within the time permitted under section 5 of the Act to continue to operate the health facility shall comply with these Regulations, notwithstanding that he is not a licensee under the Act.

Request for submission of proposals for license to establish and operate health facility.

5. (1) Any operator of a health facility of a class prescribed in regulation 3 which exists on the date of commencement of the Act shall within thirty days from that date inform the Minister through the office of the Director of Standards and Technical Services of his intention to continue to operate for a period of one year from the date of commencement of the Act and further indicate whether the operator intends to submit a proposal for a license under section 5 of the Act within that period of one year.

(2) The proposal for a license to establish and operate a health facility in accordance with these Regulations, whether it is a proposal for obtaining a license under section 5 or to establish and operate a new health facility under section 6 of the Act shall be made in **Form I** to these Regulations and shall conform to the provisions of section

6(3) of the Act, these Regulations and the generally accepted quality and standards for the health facility and services provided or proposed to be provided in the health facility.

(3) The applicant shall submit twelve copies of the proposal in **Form I** accompanied by the prescribed fee and supporting documents to the Minister through the Office of the Director of Standards and Technical Services of the Ministry of Health.

(4) The application may be delivered by hand or sent by post but when it is hand delivered, a receipt of the Ministry of Health stating the time, date and the official who received the application shall be furnished to the person delivering the application.

(5) In case the application is received by mail, the date of receipt of the documents in the Office of the Director of Standards and Technical Services of the Ministry of Health shall be reckoned as the date of the proposal and that office shall acknowledge the receipt of the package by post or e-mail immediately and in no case later than the next working day.

Scrutiny of application by the Director of Standards and Technical Services.

6. (1) Within fourteen days from the date of receipt of a proposal in the prescribed form, the Director of Standards and Technical Services shall scrutinize the proposal and where the proposal is incomplete, inform the applicant the particulars of the shortcomings for rectification within a specified time.

(2) If the Director of Standards and Technical Services finds that a proposal is in order, he shall place the proposal before the Minister for consideration for granting of a license.

Consideration of proposals by Minister.

7. (1) Within fourteen days from the date of receipt of the proposal complete in all respects, the Minister shall publish a notice in the Official Gazette that a proposal has been received by him for issuance of a licence to continue to operate a health facility operating on the date of commencement of the Act or to establish a new health facility, as the case may be, along with the particulars of the applicant, the specified location and the nature of the health facility to be established.

(2) Where a proposal for a licence to continue the operation of a health facility has been deemed to be in conformity with the provisions of section 6(3) of the Act the Minister shall cause the health facility to be inspected to ensure that the facility meets with all the minimum requirements for grant of a licence and shall take into consideration the recommendations of the inspector and the outcome of the consultation with the Chief Medical Officer and the Board of Health.

(3) Where a proposal to establish a new health facility has been *prima facie* found to be in conformity with the requirements of the Act, the Minister shall issue a provisional license in **Form II** to establish the health facility on the condition that the health facility shall meet the minimum standards prescribed prior to operating the health facility.

(4) Before issuance of a final license in **Form II** appended to these Regulations the Minister shall cause the inspection of the facility and after taking into consideration the recommendations of the inspection team and taking into consideration the outcome of the consultation with the Chief Medical Officer and the Board of Health, he shall issue a license or he may reject the application for the license specifying the reasons for such rejection.

Appointment of inspectors.

8. (1) Every person appointed to be an inspector under the Act shall possess the qualifications specified by the Minister to conduct the inspection of the health facility.

(2) The letter of appointment of an inspector shall state the name of the inspector, his qualifications, the duration of his appointment, the inspection to be carried out and the name and address of the health facilities or the local limits of his jurisdiction.

(3) The inspector shall carry out inspections from time to time so as to ensure that due compliance with the provisions of the Act are made by the licensee of the health facility.

Appointment of assessors.

9. (1) Every person appointed to be an assessor under the Act shall possess the qualifications specified by the Minister to conduct assessment of quality and standards of services provided by the health facilities.

(2) The letter of appointment of every assessor shall state the name of the assessor, his qualifications, duration of his appointment, the assessment to be carried out and the name and address of the health facility where the assessment is to be carried out and the duration of appointment.

Fees.

10. (1) The fee payable for the various services under the Act shall be as follows-

(i)	Fee for issuance of a licence to establish a hospital under the Act	two hundred thousand dollars.
(ii)	Fee for issuance of a licence to establish and operate a health facility other than a hospital under the Act	one hundred thousand dollars.
(iii)	Annual fee for renewal of a licence for a hospital	one hundred thousand dollars.
(iv)	Annual fee for renewal of a licence for a health facility other than a hospital	fifty thousand dollars.

(v)	Permission to transfer a licence ...	twenty-five thousand dollars.
(vi)	Any miscellaneous service including making a change in any entry in the licence ...	twenty thousand dollars.

(2) The Minister may waive any fee for a public sector facility.

PART II
GENERAL REQUIREMENTS

Requirements to be fulfilled by health facilities.

11. Except as otherwise provided, every health facility shall-

(a) have a policy making body on governance and administration;
(b) have a designated official responsible and accountable for medical care;
(c) have a documented administrative structure;
(d) have an individual responsible for the administration of the facility;
(e) have an updated Manual of Administrative Procedure (including operational routine, procedures and standards);
(f) have sufficient numbers of qualified staff in the employment of the health facility and present during the operating hours of the health facility commensurate with the type of services being offered at the facility;
(g) have a personnel office with files on all staff members that include certification of training;
(h) display for public information –

(i) the visiting hours, where relevant;
(ii) the names and qualifications of the medical practitioners or other professionals attending the health facility;

(i) hold staff meetings at least every quarter in a year including all categories of staff.

Maintenance of medical records of patients.

12. (1) An up-to-date medical record of each patient shall be maintained in the health facility.

(2) The medical record shall bear the assigned date for each entry made in it and shall also include the following particulars with respect to the patient-

(i) name, address and phone number, where available;
(ii) age and sex;
(iii) relevant history of illness or injury and physical findings;
(iv) diagnosis;

(v) a list or a copy of a list of all diagnostic tests and procedures carried out by the health facility on the patient, together with the date of the tests or procedures, and the results, or a copy of the results, where available, including a copy of the original test procedure;
(vi) clinical observations including results of treatment;

(vii) allergy history;

(viii) for pediatric patients, immunization records;

(ix) where there is a referral, a copy of the original referral;

(x) patient contact information;

(xi) patient consent to treatment form.

(3) The medical records and reports of patients shall be treated as confidential information and, except as provided in paragraph (4), (5), (6) or (7), no person shall be allowed to examine a patient's medical record or be given any information, copy or item from a patient's medical record.

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

(5) Copies from a patient's health record shall be provided on request to a patient or 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.

(6) Paragraph (3) does not apply to a person making a report that is required to be made under any law relating to public health or any other written law or any authority dealing with disciplinary proceedings against any health professional.

(7) Paragraph (3) does not apply to a person who is collecting data for a study that is approved by the Minister from a health facility owned or operated by the Ministry of Health or by a regional health authority, provided that the person agrees not to release or publish any identifying information.

(8) A copy of the medical record of every patient either in paper or in electronic form shall be retained for at least ten years following the last visit of the patient to the health facility.

(9) Every maternal death and death of a child under five years in the health facility shall be reported to the Chief Medical Officer within twenty–four hours of the occurrence and all other deaths shall be reported on a weekly basis to the Chief Medical Officer.

(10) The medical record unit in the health facility shall be adequately staffed to ensure that the requirements of these Regulations are met.

Equal access to care.

13. All persons seeking service at a health facility shall be treated equally regardless of age, place of birth, race, creed, nationality, gender or sexual orientation.

Patient care arrangements.

14. (1) Every health facility shall be so designed and equipped as to be able to carry out the operations that the facility is licensed for in a safe and effective manner.

(2) The waiting areas and patient registration areas of every health facility shall be readily accessible to patients, including physically challenged persons.

(3) All the areas of a health facility shall be so constructed and located as to ensure patient privacy and confidentiality without compromising patient care.

(4) Where a health facility provides emergency medical care, wheelchairs and other ambulating aids as are necessary for patients in the emergency circumstances shall be readily available at the facility.

(5) Where a health 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.

(6) Paragraph (5) does not apply with respect to a patient who is bed–ridden.

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

(8) Every health facility shall have, wherever it is possible, at least one closed wash room and a sink with running water or a clean wash-basin with a supply of potable water for hand washing.

(9) The sink or wash basin referred to in paragraph (8) shall be available near to the location where a patient is required to give specimens for laboratory examination.

(10) Where a health facility contains a medical laboratory, the sink referred to in paragraph (8) shall be in the form of a fixture that is 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.

(11) Every health facility shall have a sufficient number of flush or water carriage toilets and washrooms or toilets to handle the number of patients and employees of the facility and such toilets and washrooms shall be conveniently located for the patients and employees.

Equipment and supplies.

15. (1) In every health facility there shall be sufficient storage space for patient records and pharmaceuticals supplies.

(2) Every health facility shall establish a preventative maintenance programme to ensure that the equipment required by any manufacturer to be checked or calibrated is done with a frequency that is in accordance with the specifications of the manufacturer.

(3) Biological and other supplies requiring refrigeration shall be stored in a refrigerated enclosure and the refrigeration system should have a continuous temperature monitoring system.

(4) Infectious materials shall be stored in clearly marked containers designed specifically for storage of infectious waste that meet the requirements specified by the Guyana Bureau of Standards.

(5) Flammable liquids in excess of ten gallons shall be contained in a storage cabinet with a capacity of at least sixty gallons that meets the requirements of the Guyana Fire Service.

(6) "No smoking" signs shall be posted at areas in which flammable gases or liquids are stored.

(7) Every health facility shall install in its premises approved fire extinguishers in good working order in the number required by the Guyana Fire Service

Rights of patients.

16. (1) Every health facility shall provide the patients with considerate and 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 the medical history of the patient.

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

(4) Patients shall be informed of the identity and professional status of persons providing them care.

(5) Every member of the staff of a health facility shall wear an Identity Card with his name, photograph and position displayed prominently.

(6) The person who is responsible for coordinating a patient's care shall provide information to the patient or his authorised relative attending to him with respect to the patient's diagnosis, current prognosis, if known any treatment or procedures to be undertaken.

Consent.
Act No.7 of 1995.

17.(1) Except where otherwise provided under the provisions of the Medical Termination of Pregnancy Act 1995, no treatment or procedure shall be performed in a health facility on a patient without the voluntary, competent and informed consent of the patient or, where the patient is a minor, the consent of a relative, legal representative or guardian of the patient.

(2) For the purpose of paragraph (1), "informed consent" includes advising the patient in terms that can be understood by the patient of the risks, benefits and alternatives of all proposed treatments or procedures.

(3) Every consent under this regulation shall be in writing.

(4) Where a patient is unable to give informed consent because the patient is physically impaired, mentally impaired, debilitated or incompetent in any other way 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.

(5) Where a patient is illiterate but is otherwise able to give informed consent, the patient may give written consent by marking the consent form with the patient's mark and having it witnessed.

(6) When a patient is unable to give informed consent, and there is no relative, legal representative, guardian or other 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 and the medical practitioner who is in charge of the patient may take a decision best suited to save the life or limb of the patient.

Policies and procedures.

18. Every health facility shall have written policies and procedures that specify the scope and conduct of the care and services that it provides and those shall include at least-

(a) the mechanism used to inform a client of the medical practitioner or other health care personnel responsible for the care of the client;

(b) the keeping of patient's 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 facility is sanitary and free from nuisance;

(i) the methods used by the facility to ensure that the safety and well being of patients and employees are assured; and

(j) the mechanism used to make reports to the Ministry of Health.

Sanitation and safety.
Act No.32 of 1997.

19. (1) The occupational safety and health of persons at work in every health facility shall be the same as are required under the Occupational Safety and Health Act 1997.

(2) Every health facility shall be smoke free and the licensee shall ensure that no person smokes or holds lighted tobacco in the facility or in the nine metres radius surrounding area of any entrance or exit to the facility.

Act No.1 of 1996.

(3) The premises of every health facility shall be kept in a clean and hygienic sanitary condition and free from nuisance in accordance with the Environmental Protection Act 1996 and any other law.

(4) Syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another shall be disposed of in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(5) Every health facility shall ensure that linen, gauze, bandages or any other material that is contaminated with blood or other bodily fluid shall be treated as infectious waste in accordance with regulation 14.

(6) Any specimen collected from a patient that is transported locally in Guyana shall be transported in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government or IATA standards.

(7) Any specimen collected from a patient that is transported abroad for assessment shall be shipped in accordance with shipping guidelines as set out in *IATA Regulation 650.*

Disposal of infectious and radioactive wastes.

20. (1) Infectious waste, other than the infectious waste referred to in regulation 19(4), shall be kept separately from other wastes and shall be-

(a) stored in double impervious plastic bags that are each at least 2mm. in thickness, securely fastened and conspicuously marked "infectious waste" and when full do not exceed 25 pounds in weight.

(b) transported in receptacles that are conspicuously marked "infectious waste";

(c) processed to render the waste harmless or shall be held for pick–up in specially marked non– metal containers separate from regular waste;

(d) secure from unauthorized persons;

(e) secure from birds and animals;

(f) removed otherwise than by mechanical means or compacted;

(g) deposited other than in any sanitary landfill; and

(h) disposed of in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(2 Broken or leaking bags of infectious waste shall not be permitted to be transported from a health facility unless it is re- bagged in accordance with these Regulations.

(3) Where trash that may constitute a hazard to any person or thing is compacted and the integrity of the container is compromised, the container shall be handled as infectious waste under this regulation.

(4) All radioactive wastes shall be stored, transported and disposed of in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(5) This regulation does not apply to articles that are dirty or contaminated but are

intended to be reused after they have been cleared and sterilized.

PART III
BLOOD BANKS

Blood Banks to comply with Part III.

21. (1) Every licensee of a health facility that is licensed as a Blood Bank shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that contains a Blood Bank and every person who operates a Blood Bank under section 5 of the Act shall also ensure that the requirements of this Part are met.

Staff.

22. Every Blood Bank shall be under the supervision and direction of a medical practitioner or a pathologist.

Procedure.

23. Every Blood Bank shall meet the requirements of the Caribbean Regional Standards for Blood Banks and Transfusion Services, 2001, as amended from time to time.

PART IV
DIAGNOSTIC IMAGING FACILITIES

Diagnostic imaging facilities to comply with Part IV.

24. (1) Every licensee of a health facility that is licensed as a diagnostic imaging facility shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that provides diagnostic imaging services and every person who operates a diagnostic imaging service under section 5 of the Act shall also ensure that the requirements of this Part are met.

Staff.

25. Every facility having a diagnostic imaging facility shall be under the direct supervision of a medical practitioner.

Policies and procedures.

26.(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 the risks of the patients, personnel and the public and maximize the quality of the diagnostic information.

(2) The premises of every health facility that has an x-ray department or unit shall conform to the following structural requirements for protection from radiation:-

(i) radiation protection for the walls of the facility shall be a lead equivalent of 2 millimetres.

(ii) where there is a room above the facility, radiation protection in the ceiling of the facility shall be a lead equivalent of 2millimetres.

(iii) where there is a room below the facility, radiation protection in the floor of the facility shall be a lead equivalent of 2 millimetres.

(3) For the purposes of paragraph (2), a lead equivalent of 2 millimetres means-

(a) a single brick wall at least nine inches thick;

(b) a six inch thickness of solid concrete; or

(c) two millimetres of lead sheeting.

(4) An x–ray department or unit shall consist of an x-ray room that is at least 18 square meters, a darkroom that is at least 7.5 square metres and an office or storeroom that is at least 8 square metres in size.

(5) The waiting areas and change rooms shall be so situated that it prevents exposure to radiation.

(6) Radiation protection for patients shall consist of gonad shields, or lead rubber aprons where it is necessary to support a patient during an examination.

(7) Radiation protection for operators shall consist of-

(a) radiation monitoring badges from a recognized company or organization;

(b) lead rubbers, aprons and gloves when the operator is in the X-ray room with the patient;

(c) a control desk that is behind a lead protective screen with a lead glass window for the operator to stand behind; and

(d) radiation equipment so installed that it does not point to the control panel.

(8) The performance of equipments shall be monitored and calibration of machines shall be checked by a medical physicist at least every six months in accordance with the specifications of the manufacturer and the records of such monitoring and calibration shall be kept in the health facility and shall be readily available upon the request of an inspector.

(9) Machines in the X-ray requiring calibration shall be calibrated as soon as practicable.

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

(11) X–rays shall be taken by a diagnostic radiographer and shall be interpreted by a radiologist or, where no radiologist is available, by a medical practitioner.

(12) The X– ray equipment shall be grounded.

PART V
DIALYSIS CLINICS

Dialysis clinics to comply with Part V.

27. (1) Every licensee of a health facility that is licensed as a dialysis centre or as a dialysis clinic shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that includes a dialysis clinic and every person who operates a dialysis clinic shall ensure that the requirements of this Part are met.

Staff.

28. Every health facility licensed as a dialysis centre or that includes a dialysis clinic shall be under the direct supervision of a nephrologist.

Policies and procedures.

29. (1) Every health facility providing dialysis services to patients shall have written policies and procedures for maintaining, monitoring and evaluating 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 the risks of the patients, personnel and the public and to maximize the quality of dialysis care.

Nursing station.

30. Every dialysis clinic shall have a central nursing station.

Dialysis Treatment area.

31. (1) In every dialysis clinic, there shall be an adequate number of sinks for implementing precautionary measures relating to infection control according to standards established by the American Professions of Infection Control till alternate standards to be followed in Guyana are laid down by the Minister.

(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;
(a) water treatment area;
(b) lockers and bathrooms for patients and staff;
(c) general reception area;
(d) waiting room for patients and visitors.

Infection control. **32.** Used blood– lines and dialysers shall be treated as infectious waste in accordance with regulation 20.

Water control. **33.** The quality of water used in the dilution of dialysis concentrate shall be in accordance with AAMI water treatment equipment and quality recommendations for dialysis until alternate standards to be followed in Guyana are laid down by the Minister.

PART VI
HOSPITALS

Hospitals to comply with Part VI. **34.** Every licensee of a health facility that is licensed as a hospital and every person who operates a health facility as a hospital under section 5 of the Act shall ensure that the requirements of this Part are met.

Staff. **35.** Every hospital shall have a team of medical staff and the medical staff shall be under the direct supervision of a medical practitioner.

Accommodation. **36.** Every hospital shall have ready access to-

(a) a licensed medical laboratory, either on or off the premises;

(b) a licensed Blood Bank , either on or off the premises.

Governance and administration. **37.** (1) Every hospital shall be governed by a policy making body and its by– laws shall include a written administrative medical care in the hospital.

(2) Every hospital shall designate a person who is responsible for and accountable for continuing medical care in the hospital.

(3) The by– laws of every hospital shall-

(a) provide for a manual of administrative procedures to be employed by the hospital;
(b) require a personnel office that contains a list of all medical practitioners and paramedical professionals on the hospital staff with their qualifications and training;

(c) require staff meetings at least once a month and the meetings shall include of all categories of staff;

(d) set out the visiting hours of the hospital and require them to be prominently displayed to the public;

(e) require a medical practitioner, or where a medical practitioner is not available, a Medex, to be on duty twenty–four hours per day;

(f) require daily rounds of the wards of the hospital;

(g) provide that a specific person or persons shall be responsible during daily rounds for following up on each patient who is admitted to the hospital;

(h) require that the staff on duty in the hospital shall know how to contact all medical staff who are on duty at any particular time;

(i) provide for written procedures to deal with the preparation and sterilization of all materials of the hospital;

(j) provide for written procedures to ensure that cleaning takes place in standardized fashion including instruction for the use of disinfectants and the elimination of biological and other wastes;

(k) provide for a designated individual who shall be responsible for ensuring that the hospital is cleaned on a daily basis; and

(l) require the establishment of a protocol to deal with highly contagious diseases.

Emergency services.

38. (1) Every hospital shall have an emergency department that is located at a specific easily accessible dedicated site at the hospital and that has a medical practitioner and a nurse available on duty twenty–four hours a day with the duty chart prominently displayed at a conspicuous place.

(2) The emergency service shall have adequate provision of life saving First Aid medicines and equipments.

(3) The emergency service at a hospital shall include an arrangement to refer the patient to the nearest facility that has the capability of providing the specialty service required by the patient.

Food service.

39. (1) Food services in a hospital shall be supervised by a dietician or food service supervisor who shall maintain or ensure the maintenance of a list of diets appropriate for the pathology of the types of patients served by the hospital.

(2) A diet manual shall be available at all times.

(3) Each food service worker shall be-

(a) the holder of a valid food handlers certificate issued by the municipality or public health department where the worker is employed, as the case requires; and

(b) so dressed as to make him easily identifiable as a food service worker.

(4) The food preparation area in a hospital shall be-

(a) so constructed that all external openings to the area are fly–proof; and

(b) restricted to food service workers only.

(5) Patients on special diets shall not be permitted to receive food from sources external to the hospital except as provided in paragraphs (6) and (7).

(6) Where the food service in a hospital is contracted out, the hospital shall ensure that-

(a) all patient diets are monitored by a dietician or food service supervisor; and

(b) the contract with the external supplier provides for inspection under the Act.

(7) When any relative of a patient or other person desires to bring food for a patient he shall consult and obtain prior permission of the competent authority of the hospital.

(8) Food for patients shall be covered from the time it leaves the food preparation area until it reaches the patient.

Sterilization.

40. Every hospital shall have access to a specific dedicated site for the preparation and sterilization of materials of the hospital.

(2) The sterilization equipments shall consist of an autoclave, instrument sterilizer and a stove or oven and shall be tested regularly and at least twice a year to ensure that they are in proper working order to sterilize the materials being placed in them.

Dispensing of drugs.

41. (1) Every hospital shall have a specific site that is dedicated for the pharmacy and the site shall provide for the conservation and refrigeration of drugs.

(2) The pharmacy in a hospital shall be administered and controlled by a pharmacist who provides drugs to in–patients and to out–patient clinics of the hospital on a restricted schedule to be fixed by the hospital administration and to the emergency department on a twenty–four hour basis.

(3) The hospital pharmacist shall keep a medication profile for each patient receiving drugs from the pharmacy.

Registers and indexes.

42.(1) Every hospital shall keep the following registers:-

(i) register of admissions and discharges for both in–patients and out– patients;
(ii) emergency department register;
(iii) operating room register;
(iv) maternity ward register;
(v) register of births;
(vi) register of deaths.

(2) Every hospital shall keep the following indexes:-

(i) master index of patients;
(ii) operating index;
(iii) disease index;
(iv) staff index.

Occupational safety and health. Act No.32 of 1997.

43. (1) The administrator of every hospital shall ensure that one or more health and safety representatives are chosen from amongst the staff in the hospital in accordance with the provisions of the Occupational Safety and Health Act 1997.

(2) No person shall be employed by a hospital unless the person has been medically examined by a medical practitioner provided by the hospital and found fit for employment.

Quality assurance.

44. (1) In addition to the by– laws referred to in regulation 37, every hospital shall have by–laws that establish a quality assurance programme for the hospital that evaluates the quality of care being provided to patients of the hospital on an on–going basis against a prevailing and accepted standard of professional care.

(2) Every quality assurance programme referred to in paragraph (1) shall-

(a) ensure that all patient care services are efficiently rendered, readily available and properly documented;

(b) ensure that all hospital staff are ethically, professionally, competent and duly qualified for their particular duty in the hospital;

(c) establish a system to evaluate the hospital's facilities, manpower, necessary drug supply and physical safety of workers;

(d) establish protocols to investigate and resolve problems that could negatively impact on the quality of patient care;

(e) establish a system of setting priorities to deal with quality assurance issues to ensure that the problems are investigated and resolved so that the issues may not negatively impact on the quality of patient care; and

(f) establish a system of monitoring, evaluating and documenting the results of the hospital quality assurance programme.

Housekeeping.

45. (1) All floors of the hospital shall be washed at least once a day with cleaning agents recommended or consistent with the recommendations of the manufacturer of the flooring.

(2) Dry sweeping shall not be permitted except in areas meant for out–patients.

(3) Every hospital shall have suitably protective clothing available for staff who may have to come into contact with highly infectious patients or materials.

PART VII
OUT – PATIENT CLINICS

Out-patient clinics to comply with Part VII.

46. Every licensee of a health facility that is licensed as an out– patient clinic and every person who operates an out-patient clinic under section 5 of the Act shall ensure that the requirements of this Part are met.

Policies and procedures.

47. (1) Every out–patient clinic shall exhibit at a conspicuous place the names and qualifications and specializations, if any, of the medical practitioners who are available at the clinic and the times at which they are available.

(2) Every out–patient clinic shall have written policies governing visiting of patients at the clinic.

(3) Every out–patient clinic of a hospital shall be under the directions of its medical director or a designated medical practitioner of the hospital.

PART VIII
MATERNITY WARDS IN HOSPITALS AND HEALTH CENTRES

Maternity wards to comply with Part VIII.

49. Every licensee of a health facility that is licensed as a hospital or health centre that operates a maternity ward and every person who operates a maternity ward under section 5 of the Act shall ensure that the requirements of this Part are met.

Staff.

50. (1) Every maternity ward in a hospital shall be under the supervision and direction of a medical practitioner.

(2) Every maternity ward in a health centre shall be under the supervision and direction of a medical practitioner or a medex or a staff nurse or a midwife.

Competent staff to manage maternity care.

51. (1) The patients in labour in a maternity ward shall be managed by a staff nurse or midwife under the direct supervision of the medical practitioner or Medex who is responsible for the care of patients.

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

(3) Nursing and maternity care in a hospital shall be set out in an organisational chart and the maternity ward shall meet the following criteria-

(i) Evidence of current registration of all nurses and midwives shall be available on request.
(ii) A roster of nurses and midwives on various shifts within each twenty– four hour period for the week shall be available upon request.
(iii)Vital signs of each patient shall be observed and recorded on each patient's chart at least once in 24 hours or as often as is required in the circumstances.

Accommodation.

52. Every maternity ward shall have and maintain at all times-

(a) at least one delivery room; and

(b) operable resuscitation equipment including a supply of oxygen and suction apparatus commensurate with the number of patients in the facility.

Surgical operations.

53. Every maternity ward in which surgical operations are performed shall meet the requirements of **Part XII** (Surgical Centres).

PART IX
MEDICAL LABORATORIES

Medical laboratories to comply with Part IX.

54. (1) Every licensee of a health facility that is licensed as a medical laboratory shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that contains a medical laboratory and every person who operates a medical laboratory under section 5 of the Act shall ensure that the requirements of this Part are met

Staff.

55. (1) Every medical laboratory shall be under the supervision and direction of a medical practitioner

(2) Every medical laboratory shall have on staff medical laboratory 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.

56. Every medical laboratory shall display a list of all tests that are carried out by the health facility along with the details of fees chargeable for each test and those tests that are carried out by any other facility on behalf of the laboratory.

Collection of specimen.

57.(1) The collection of specimens shall only be performed under the general supervision of the laboratory director or a medical laboratory technologist.

(2) Every medical laboratory shall post in a conspicuous place in the laboratory, written instructions for the handling, timings of collection of samples or specimen, preservation, storage and transportation of specimens and timing of delivery of test reports.

Records and reports.

58. (1) Every medical laboratory shall keep records and reports of all tests undertaken at the health facility and those that are carried out by any other health facility on behalf of the laboratory.

(2)True copies of all records and reports of tests performed including the reports received from any other laboratory, shall be kept on the premises of the requesting laboratory and the laboratory that performed the tests, for a period of ten years.

(3) The records and reports referred to in this regulation may be kept in electronic form provided they can be reproduced in a readable form at any time during the period of retention in terms of paragraph (2).

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

Policies and procedures.

59. (1) Every medical laboratory shall have written policies and procedures that address the following matters -

(i) quality system requirements;
(ii) organisation;
(iii) purchasing of equipments and supplies;
(iv) complainsts against the laboratory;
(v) review of requests;
(vi) control of non-conforming work and corrective and preventive action;
(vii) control of records and documents;
(viii) quality assurance and management reviews;
(ix) safety;
(x) personnel;
(xi) accommodation and environmental conditions;
(xii) test methods and sampling;
(xiii) equipment;

(xiv) handling of tests and calibration of instruments;
(xv) assuring quality of test results and reporting of test results.

(2) A medical laboratory shall not be used unless it is certified by the Guyana Bureau of National Standards as meeting the requirements of paragraph (1).

Reportable disease.

60. (1) Every medical laboratory shall report to the Ministry of Health the particulars of those tests that a medical practitioner is required to report under the existing laws.

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

Accommodation.

61. (1) All medical laboratories shall be well ventilated and, where possible, air conditioning that is independent from the rest of the facility shall be used.

(2) In every medical laboratory which uses toxic and volatile chemicals, fume hoods that safely vent out toxic and vapors shall be installed

(3) At the premises of every medical laboratory fire blankets with instructions for proper use shall be kept on.

(4) In every medical laboratory written fire control and evacuation plans together with clearly marked fire escape routes shall be posted in one or more conspicuous places.

(5) Every medical laboratory that uses electronic equipment requiring electrical power 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 X
ONCOLOGY CLINICS

Oncology clinics to comply with Part X.

62. Every licensee of a health facility that is licensed as an oncology clinic shall ensure that the requirements of this Part are met.

Requirement of medical practitioner and staff.

63. (1) A health facility that is licensed as an oncology clinic and every person who operates an oncology clinic under section 5 of the Act shall be under the supervision and direction of a medical practitioner with specialty training in oncology.

(2) A clinic in which medical oncology is provided shall be under the supervision and 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 health facility that is licensed as an oncology clinic shall have on duty during the

hours of operating, 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.

Examination of tissues.

64. (1) The tissue that is removed from a patient in an oncology clinic shall be sent to a pathologist for an examination.

(2) If on examination of the tissue, the pathologist finds any malignancy, it shall be reported to the oncology clinic and the oncology clinic shall place a copy of the report in the record of the patient and report the fact to the Ministry of Health.

Administration of chemo-therapeutic agents.

65. Every health facility in which chemotherapy is administered shall have written policies and procedures with respect to the preparation of drugs that ensures the safety of the members of the staff and patients.

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

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

(4) Every health facility in which chemotherapy is administered shall obtain a written consent from the patient or a legal representative of the patient before administering chemotherapy drugs.

(5) Where a patient is receiving chemotherapy drugs at home, the health facility shall provide instructions to the patient or, where applicable in the circumstances, to any other person who may be assisting the patient or administering the drugs to the patient.

PART XI
PATHOLOGY AND CLINICAL LABORATORY FACILITIES

Pathology and clinical laboratories to comply with Part XI.

66. Every licensee of a health facility that is licensed as pathology and clinical laboratory facility and every person who operates a pathology and clinical laboratory under section 5 of the Act shall ensure that the requirements of this Part are met.

Accommodation.

67. Every pathology and clinical laboratory facility shall designate separate areas for the procurement and storage of specimens and placing of infectious waste for disposal.

Tracings.

68. Every pathology and clinical laboratory facility shall ensure that abnormal ECG tracings shall be confirmed by an internist or a cardiologist.

PART XII
SURGICAL CENTRES

Surgical centres to comply with Part XII.

69. Every licensee of a health facility that is licensed as a surgical centre and ever hospital that operates a surgical centre and every person who operates a surgical centre under section 5 of the Act shall ensure that all the requirements of this Part are met.

Supervision and staff.

70. (1) Every surgical centre shall be under the supervision and direction of a medical practitioner.

(2) Every surgical centre where general intravenous or any other type of a regional anesthesia is being administered shall have on staff an anesthesiologist, a nurse and an anesthetist or a medical practitioner with specialty training in anesthesiology .

Policies and procedures.

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

(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 anesthesia services that may be performed in the centre and the locations where such anesthesia services may be administered;

(c) the available pre–operative and post operative transportation;

(d) the available post-operative care including post anesthesia recovery;

(e) standardized procedures for operating and maintaining operating rooms and instruments;

(f) procedures for cleaning and disinfecting surgical areas between operations; and

(g) protocols for regular microbiological testing of the surgical area.

(3) Every patient in a surgical centre who receives anesthesia, other than local anesthesia, shall be examined before discharge and shall be accompanied to home by a

person designated by the patient or the person taking care of the patient.

(4) The examination referred to in paragraph (3) shall be performed by a medical practitioner or a dental 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 dental surgeon for postoperative problems.

(6) Whenever feasible, a family member shall be available to pediatric patients during the preoperative and postoperative periods.

Physical requirements.

72. (1) In every surgical centre, the surgical areas shall be separate and distinct from the rest of the health facility.

(2) A site separate from the surgical area shall be set aside for use of the surgical staff and nursing staff for washing and hanging of clothes.

(3) Every surgical centre shall have emergency power supply available during power failures.

Patient's history to be recorded.

73. (1) Before a patient is submitted to any anesthetic 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.

(2) Where in the opinion of the operating surgeon, compliance with paragraph (1) would result in delay and 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.

74. 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.

Operations Register.

75. Every surgical centre shall keep an operation register showing the name of the patient, the date and nature of the operation, the name of the surgeon, the name of the anesthesiologist or nurse anesthetist given and the time the operation began and was completed.

Anesthetic.

76. The anesthesiologist or nurse anesthetist shall furnish to the surgical centre, a record showing the type of anesthetic given, the amount used, the length of time the anesthetic was administered to the patient and the condition of the patient following the operation.

Surgical procedures.

77. An accurate and completed 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.

Examination of tissues.

78. (1) Any tissue removed from a patient during an operation or during oral surgery shall be set aside, preserved and labeled by the operating surgeon and sent to a Medical Laboratory for examination by a pathologist.

(2) The report of the pathologist received by the Surgical Centre shall become part of the patient's medical record and all abnormal findings reported by the pathologist shall be reported to the Chief Medical Officer.

FORM I

[*See* reg.5 (2) and (3)]

APPLICATION FOR ISSUANCE OF A LICENCE TO ESTABLISH AND OPERATE/CONTINUE TO OPERATE A HEALTH FACILITY UNDER THE HEALTH FACILTIES LICENSING ACT 2007 (ACT NO. 26 OF 2007)

To

The Minister of Health,
Guyana, Georgetown.

I /We hereby apply on behalf of .....(name of the person/company/firm) for issuance of a license under the Health Facilities Licensing Act 2007 to establish and operate/continue to operate the following health facility:-

Tick mark or specify the relevant health facility in respect of the application

Diagnostic Imaging Facilities

Dialysis Centres or Dialysis Clinic

Health Centres

Hospitals

Human Tissue Banks

Maternity Wards

Medical Laboratories

Nursing Homes

Oncology Clinics with Radiation Therapy

Pathology and Clinical Laboratory

Surgical Centres

Any other health facility as prescribed under section 2 of the Act:

I/We furnish the following information relating to the proposal:

1. Full name of the applicant and in case the applicant is an individual, his qualifications and occupation:

2. Postal address of the applicant with telephone number(s):

3. Name of the health facility:

4. Date from which the health facility has been established/proposes to be established:

5. Particulars of the business and professional experience of the person(s) submitting the proposal:

6. Description of the location and postal address of the building(s)where the health facility is situated or proposed to be established:

7. A statement of the interest of the applicant in the building in respect of which the license to establish and operate/continue to operate a health facility is applied for:

8. Details including nature and cost of the

services to be provided in the health facility

9. Details of physical requirements of the proposed health facility:

10. Projected planning, capital and operating cost of the health facility:

11. Revenue source (s) of the costs:

12. Financial viability of the health facility:

13. Role of the proposed health facility and services proposed to be offered in it in the context of the National Health Plan and other Action Plans of the Ministry of Health:

14. Details of the system that will be established to ensure the monitoring of the results of the service(s) to be provided in the health facility:

15. Details of the nature, source and training of the professional staff proposed for the health facility:

16. Detailed drawing/ sketch plan of the building and other structures of the health facility proposed to be utilized:

17. Date from which the health facility is proposed to be established and operated:

18. A statement of sanitary arrangements, ventilation and water supply of the building:

19. A statement as to the arrangements, if any, for feeding of patients:

20. A statement on the fire escapes of the building and the facilities provided for use in case of fire:

21.If it is proposed to offer services in surgery, gynaecology or obstetrics, a statement as to the type of surgery, gynaecology or obstetrics to be performed and as to the facilities and equipment which

are to be provided in the building for these purposes including facilities for anaesthesia:

22. The number of professional and administrative staff of the facility and the qualification of each member of such staff (existing and proposed to be filled up separately):

23. Any other information relevant to the requirements and limitations specified in the request for the proposal determined by the Minister of Health :

24. A statement as to the classes of patients, if any, proposed to be admitted:

25. Details of payment of prescribed fee for licence:

26. Any other information which the applicant considers relevant for the proposal:

27. List of enclosures:

I/We hereby certify that the above particulars are correct and best to my/our knowledge.

.....(A)

Place: **(Signature)**

Date:

.....(B)

(Signature)

FORM II

[*See* reg. 7(3) and (4)]

(National Emblem)

LICENCE TO ESTABLSH AND OPERATE/CONTINUE TO OPERATE HEALTH FACILITY UNDER THE HEALTH FACILITIES LICESING ACT 2007 (ACT No.26 OF 2007)

***

Provisional Licensee/ License is granted to

.....

to establish and operate/continue to operate a health facility of..... from .....20 ... to 20....

(here specify the relevant prescribed category of health facility) in accordance with the Health Facilities Licensing Act 2007 (Act No.26 of 2007) subject to the following terms and conditions and to such additional conditions as may be endorsed on the back of this license:-

Premises at which the health facility shall be operated:

Terms and conditions:

Place:
Date:

Signature and seal of the Licensing authority.

Additional conditions, if any.

Renewals and endorsements:

Made this 14th day of April 2008.

Minister of Health.