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**REGULATIONS GOVERNING PRIVATE HOSPITALS AND UNATTACHED  
OPERATING THEATRE UNITS**

Published under Government Notice No. R. 158 of 1 February 1980

**As amended by:**

Government Notice No. R.696 of 3 April 1980  
Government Notice No. R. 2687 of 16 November 1990  
Government Notice No. R.434 of 19 March 1993

The Minister of Health has, by virtue of the powers vested in him by section 44 of the Health Act, 1977 (Act 63 of 1971), made the following regulations:

**Definitions**

1. For the purposes of these regulations, unless the context otherwise indicates-

**“approved”** means approved by the Head of Department.

**“central sterile supply department”** means a room or rooms in which instruments, dressings, basins, containers, water and other items which are required to be sterile for the treatment of patients are sterilised, and are for this purpose received, cleaned, packed, sterilised and stored;

**“demarcated area”** means an area which divides sterile from non-sterile areas;

**“Director”** means the Chief Executive officer responsible for hospital services of the provincial administration of a province within which a particular private hospital or unattached operating-theatre unit is or is to be situated;

**“Head of Department”** means the Head of the Department of Health Services and Welfare, Administration: House of Assembly;

**“inspecting officer”** means an officer as defined in section 1 of the Public Servants Act, 1957 (Act 54 of 1957), or an officer or employee employed in terms of a Provincial Ordinance in a Provincial Hospital Service, authorised in writing by the Secretary to carry out an inspection;

**“lighted”** in relation to any room, means that such room is effectively lighted by means of an approved artificial lighting system or that the total unobstructed window area is equivalent to not less than 15 per cent of the floor area of such room;

**“Minister”** means the Minister of Health Services, Welfare and Housing: House of Assembly;

**“operating-theatre”** means a room in which a registered medical practitioner or dentist carries out operations;

**“operating theatre-unit”** means a place where surgical activities are carried out and in which provision is made for those facilities as set forth in these regulations;

**“overcrowded”**, in relation to any room of accommodation, means that there is less than 4m<sup>2</sup> of floor area and less than 12m<sup>2</sup> of air space for each person working or accommodated in such room or accommodation and less than half of this area and space for each such person under 10 years of age: Provided that the floor area and air space of a single room shall not be less than 10m<sup>2</sup> and 30m<sup>2</sup> respectively;

**“prescribed procedures”** means the surgical operations and medical procedures listed in Annexure A;

**“private hospital”** means any hospital or any other institution, building or place at which provision is made for the treatment and care of cases requiring medical or surgical treatment and nursing care, but excluding -

- (a) a hospital or any such institution, building or place conducted by the State, a provincial administration, local authority, private hospital authority, hospital board or any other public body;
- (b) any consulting room, surgery or dispensary of a medical practitioner or dentist which does not provide any bed accommodation;
- (c) an unattached operating-theatre unit; and
- (d) a hospital or other institution licensed for the reception and detention of mentally ill persons in terms of section 46 of the Mental Health Act, 1973 (Act No. 18 of 1973); and
- (e) an institution, building or place for the treatment or nursing care of aged people attached to an old age home as defined in the Aged Persons Act, 1967 (Act No. 81 of 1967), or a housing development scheme as defined in the Housing Development Schemes for Retired Persons Act, 1988 (Act No. 65 of 1988);

**“proprietor”** means the person, or the nominee in the case of a company or an association of persons (whether corporate or incorporate), who establishes, extends, conducts or maintains a private hospital or unattached operating theatre-unit;

**“recovery room or area”** means that section of an operating theatre-unit specially set aside and fully equipped, for the immediate post-operative recovery, resuscitation, nursing and special care of patients until such time as such patients are considered to have recovered sufficiently to be safely removed from the aforementioned section;

**“sluice room”** means a room where bed pans, urinals, sputum mugs and similar containers are kept and can be emptied, washed out, disinfected and stored, and where soiled linen, dressings and similar items can be deposited prior to removal:

**“treatment”** means any diagnostic or therapeutic procedure carried out for surgical, medical, obstetrical or dental purposes and includes the provision of the necessary nursing services, accommodation, equipment and ancillary facilities, and **“treat”**, **“treating”** and **“treated”** have corresponding meanings;

**“unattached operating theatre unit”** means an operating-theatre unit not owned or managed by the State, a provincial administration, a local authority, a private hospital authority, a hospital board or any other public body and not attached to a hospital or nursing home, and where a patient operated on in such operating-theatre unit may remain

for a period not exceeding 12 hours, reckoned from the time he enters the unit immediately before being operated on; and

“**ventilated**”, in relation to any room, means that such room is ventilated by an effective artificial ventilation system or by one or more windows opening direct to the outer air and capable of opening wholly or partly, and so placed as to make possible an effective through draught or cross-ventilation.

Any other expression in these regulations has the same meaning, unless the context clearly indicates otherwise, as that assigned to it in the Health Act, 1977 (Act 63 of 1977).

### **Registration**

2. Subject to the provisions of regulation 8, no person shall erect, establish, extend, conduct, maintain, manage, control or render any service in a private hospital or an unattached operating-theatre unit or permit or arrange for treatment to be provided therein unless such private hospital or unattached operating-theatre unit or proposed private hospital or unattached operating-theatre unit has been registered in accordance with the provisions of these regulations and the proprietor is in possession of a valid certificate of registration issued to him in respect thereof by the Head of Department.
3. Each such certificate of registration issued in terms of regulation 14(1) or 14(3) shall be effective from the date of issue up to and including the next succeeding 31st day of December, when it shall lapse, or for such portion of the said period as may be specified in the certificate of registration. An application for the renewal of such certificate of registration shall be made in accordance with regulation 11, not less than 90 days before the date of expiry: Provided that whenever such registration certificate is issued after 30 September, such registration certificate shall be issued for a period up to 31 December of the following year.
4. A private hospital or unattached operating-theatre unit shall not be registered as such and no certificate of registration shall be issued in respect thereof, unless-
  - (1) the premises on which a private hospital or unattached operating-theatre unit is or is to be conducted and the equipment which is used or is intended for use in such private hospital or unattached operating-theatre unit are suitable and adequate for the purposes of the said private hospital or unattached operating-theatre unit;
  - (2) the private hospital or unattached operating-theatre unit is not managed or will not be managed in a manner which will be detrimental to the physical, mental or moral welfare of the patients or staff;
  - (3) the staff of the private hospital or unattached operating-theatre unit comply with, or will comply with, accepted standards for the purposes of such hospital or unit;
  - (4) the person in charge of such private hospital or unattached operating-theatre unit is or will be registered as a medical practitioner or, in the case of an exclusively dental service, a dentist, in terms of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974), or in the case of a general medical nursing service or a midwifery service, is or will be registered in terms of the Nursing Act, 1978 (Act 50 of 1978), as a registered nurse or midwife, respectively;
  - (5) a nurse registered in terms of the Nursing Act, 1978 (Act 50 of 1978), is or will be in charge of the nursing service if the person in charge is a registered medical

- practitioner or dentist as described in subregulation (4); and
- (6) such registration is in the public interest.
5. (1) In his application the proprietor shall give a description of the premises and also furnish particulars regarding their location, the nature of the treatment to be rendered there, the population groups of the staff attached to the private hospital or unattached operating-theatre unit and the population groups that will make use of the private hospital or unattached operating-theatre unit, and shall furnish any further information required by the Head of Department in order to consider the application.
- (2) The proprietor shall immediately report to the Head of Department in writing any change in the particulars furnished by him in terms of subregulation (1) or indicated on the current certificate of registration issued in terms of regulation 12 of these regulations.
6. The proprietor of a registered private hospital shall give not less than three months' notice in writing of the intended closure of such hospital to the Head of Department, the Director, patients and staff: Provided that, in exceptional circumstances, the Head of Department may authorise a shorter period of notice.

#### **Establishment of private hospitals and unattached operating-theatre units**

7. (1) No person shall erect, alter, equip or in any other way prepare any premises for use as a private hospital or unattached operating-theatre unit without the prior approval in writing of the Head of Department.
- (2) (i) Any person intending to establish a private hospital or an unattached operating-theatre unit shall first obtain permission in writing from the Head of Department, who, after consultation with the Director, shall satisfy himself as to the necessity or otherwise for such a private hospital or unattached operating-theatre unit before granting or refusing permission.
- (ii) Having obtained such permission, the applicant shall complete Form I (Annexure B) and submit plans for approval by the Head of Department, together with the necessary information, and shall supply any additional information which the Head of Department may require.
- (3) Permission and approval in terms of regulation 7 are not transferable.
8. In the case of a private hospital or unattached operating-theatre unit of which the buildings are still to be erected or converted, plans of the buildings or proposed buildings shall accompany the application for registration. The plans should show clearly the nature and construction of the buildings or proposed buildings or the nature of the conversions, as the case may be. Room names, dimensions and square measurements shall be attached to the plans in the form of a schedule.
9. A sufficient number of lifts or ramps shall be provided where patients are housed in a multi-storey building: Provided that adequate provision shall be made for lifts suitable for taking a patient bed or trolley and for the separate removal of soiled linen, waste and refuse.

10. All plans shall be drawn to the scale of 1:100 and submitted in duplicate
11. The applicant shall furnish the Head of Department with proof, in writing that neither the Government departments concerned nor the local authority concerned have any objection to the private hospital or unattached operating-theatre unit being conducted on the premises concerned. In the case of a building still to be erected or converted, the applicant shall furnish proof, in writing, that the plan has been passed by the local authority concerned.

#### **Application for renewal of registration**

12. Not less than 90 days before the date on which a certificate of registration expires, the proprietor shall apply for the renewal of such registration.
13. Every application for renewal of registration of a private hospital or unattached operating-theatre unit shall be made to the Head of Department substantially in the form of Form I in Annexure B.

#### **Handling of applications**

14. Upon the receipt of an application the Head of Department shall, after consultation with the Director, decide-
  - (1) to register the proposed private hospital or unattached operating-theatre unit and issue a certificate of registration in respect thereof, subject to such conditions as he may deem fit; or
  - (2) to refuse registration, in which event he shall not issue any certificate of registration; or
  - (3) to renew the registration of the private hospital or unattached operating-theatre unit and issue a certificate of registration in respect thereof, subject to such conditions as he may deem fit; or
  - (4) to refuse the renewal of registration, in which event no certificate of registration shall be issued.
15. The Head of Department may for the purposes of regulation 14 carry out or cause to be carried out by an inspecting officer an inspection of the premises in respect of which the application was made and the applicant shall pay to, the Receiver of Revenue in respect of such inspection an inspection fee of R30, which shall include transport fees.

#### **Re-application for registration**

16. Any proprietor who has applied for registration of a private hospital or unattached operating-theatre unit and whose application has been refused or any proprietor whose application for renewal of registration has been refused or whose certificate of registration has been cancelled in terms of regulation 18 or any proprietor who failed to apply timeously for renewal of registration and whose certificate of registration has expired or any proprietor or prospective proprietor who lodged an appeal in terms of regulation 55 against the refusal by the Head of Department of registration or renewal of registration or against the cancellation by the Head of Department of a certificate of registration and whose appeal has been dismissed may at any time re-apply for registration or renewal of registration of the same private hospital or unattached operating-theatre unit: Provided

that, if registration or renewal of registration has been refused or the certificate of registration has been cancelled because of failure by the applicant to comply with all the conditions and requirements imposed by the Head of Department in terms of regulation 14(1) or 14(3), such further application shall not be made until and unless all such conditions and requirements have been complied with.

### **Exemption from requirements in respect of registration**

17. The Head of Department may at any time, on such conditions and for such period as he may determine, grant a proprietor exemption from any requirements in respect of registration in terms of these regulations.

### **Cancellation of certificate of registration**

18. A certificate of registration may at any time be cancelled -
- (1) by the Head of Department if the proprietor-
    - (i) fails to comply with any conditions and requirements imposed in terms of regulation 14(1) or 14(3); or
    - (ii) fails to furnish the returns, particulars or information which he is required to furnish in terms of regulation 28; or
    - (iii) is found guilty of an offence in terms of the provisions of these regulations;
  - (2) by the Head of Department or the Minister if he deems be in the public interest that the private hospital or unattached operating-theatre unit in respect of which such certificate of registration has been issued be closed.
19. Whenever the Head of Department or the Minister, as the case may be cancels a certificate of registration in terms of regulation 18 he shall give notice in writing to the proprietor that he is so cancelling the certificate of registration and that the private hospital or unattached operating-theatre unit in respect of which it was issued shall be closed down on or before a date specified in such notice.
20. Upon the cancellation of a certificate of registration in terms of regulation 18, the registration of the private hospital or unattached operating-theatre unit in respect of which such certificate of registration was issued shall lapse on the date specified in the written notice referred to in regulation 19.

### **Building requirements for unattached operating-theatre units**

21. The rooms of an unattached operating-theatre unit shall comply with the following requirements:
- (1) Save where otherwise required in these regulations, all walls shall not be less than 2,6 m high, measured from the floor to the ceiling, and shall be constructed of burnt brick, stone, concrete or some other impervious material and, unless otherwise approved, the external walls shall be not less than 225 mm thick and the internal walls not less than 89 mm thick.
  - (2) In the operating-theatre, sluice room, toilets and shower cubicles, the joint between the walls and the floor shall be rounded.
  - (3) All corridors taking patient trolleys shall be not less than 2 m wide.
  - (4) All doors giving access to rooms in which patients are to be accommodated shall

- be not less than 2 m high and 1m wide.
- (5) All rooms shall be satisfactorily ventilated and lighted and spacious enough to ensure that they are not overcrowded when the maximum number of persons that would normally be in them at any time are present.
  - (6) All rooms, corridors and theatres shall be provided with a smooth, dustproof ceiling.
  - (7) The floors of all rooms and corridors shall be of approved material and covered with impervious washable material: Save that where flammable materials are used, kept or stored, the floor of the operating-theatre and the rooms where such flammable materials are used, kept or stored, as well as all floors within a distance of 1m of the doors of the operating-theatre and of such rooms where flammable materials are used, kept or stored, shall be covered with antistatic material of a washable impervious type and that a conspicuous cautionary notice is a requirement if the floor is not antistatic.
  - (8) The surfaces of the walls shall be smoothly plastered and, save where otherwise provided in this regulation, be painted with washable paint of a light colour or clad with a washable impervious material: Provided that in the case of sluice rooms, toilets, shower cubicles, operating-theatres, central sterile supply departments or sterilising rooms, the walls up to a height of not less than 2,1m from the floor may, instead of being painted with washable paint of a light colour, be covered with white or light-coloured glazed tiles or other washable, impervious material: Provided further that the walls behind all wash-hand basins shall, up to a height of 500mm above and 500mm on either side of such wash-hand basins, be covered with white or light-coloured glazed tiles or other washable, impervious material.
  - (9) Properly placed and adequate fire-hydrants, fire-hoses, fire-extinguishers, fire-escapes and emergency exits shall be provided and satisfactorily maintained.
  - (10) If the operating-theatre unit is in a multi-storeyed building and not on the ground floor, the building shall be equipped with fire-escape stairs as well as a lift of sufficient size to take a patient stretcher.
  - (11) Sufficient water shall be laid on to all taps, showers, sluicing apparatus and sanitary conveniences in the operating-theatre unit and all waste water from wash-hand basins, sluice rooms, sluice pans and toilet pans shall effectively drain into an approved sewerage system.
  - (12) An incinerator or other suitable system shall be provided for the effective incineration or disposal of soiled dressings and surgically removed tissues, without causing any nuisance.

### **Rooms required**

22. An unattached operating-theatre unit shall be conducted in accommodation in which provisions is made for-
  - (1) an operating-theatre with adjoining sterilising room and recovery area and ward accommodation so planned or conducted that male and female patients shall be effectively separated: Provided that if such recovery area is so arranged as to provide adequate substitute ward accommodation, no such separate ward accommodation shall be required;
  - (2) a scrubbing-up area outside the operating-theatre: Provided that in the operating-theatre is sufficiently spacious for the purpose, such scrubbing-up area may be provided at a suitable place within the operating-theatre; and
  - (3) a sluice room, sluicing facilities, nurses' duty-room facilities, a linen room or

cupboard for clean linen, storage space for flammable material, adequate change-room and toilet facilities for staff and patients separately (toilets, independent from change-rooms may be provided, for males and females separately), a waiting-room for patients and their visitors, office space and, where applicable, a consulting room.

### **Accommodation**

23. The rooms referred to in regulation 22 shall comply with the following requirements:
- (1) The waiting-room shall have a floor area of not less than 12m<sup>2</sup>, with a minimum wall length of 3 m: Provided that if the office space is to be provided inside the waiting-room the floor of the waiting-room shall have an area of not less than 18m<sup>2</sup> and a minimum wall length of 3,6m.
  - (2) The office space shall -
    - (i) have a floor area of not less than 6m<sup>2</sup> if a portion of the waiting-room is set aside for this purpose; or
    - (ii) be provided in the form of a separate room, with a floor area of not less than 10m<sup>2</sup> and a minimum wall length of 2,4m.
  - (3) The consulting room, if provided, shall be outside the operating-theatre area and shall have a floor area of not less than 12m<sup>2</sup> and a minimum wall length of 3m and shall be fitted with at least one wash-hand basin with sufficient hot and cold water laid on.
  - (4) The operating-theatre shall have a floor area of not less than 20m<sup>2</sup>, and a minimum wall length of 3,6 m. The walls shall be not less than 2,6 m high, measured from the floor to the ceiling, and shall have a continuous, smooth surface and be painted with hard glossy epoxy resin or a similar paint or covered with any other suitable washable impervious material; the ceiling shall be painted with a light-coloured enamel paint. The walls, the floor and the ceiling shall be capable of withstanding repeated cleansing and disinfection.
  - (5) In the scrubbing-up area, hot and cold water shall be laid on to elbow-operated taps over two wash-hand basins or troughs.
  - (6) The operating-theatre shall be effectively ventilated and lighted: Provided that windows, if any, shall be dustproof. The minimum requirement for air conditioning shall be the installation of an office type conditioning unit with a 10 micron dust filter.
  - (7) The operating-theatre shall be provided with electric power to at least three flashproof wall plugs. I a suitable electric operating-theatre lamp suspended from the ceiling or cantilevered from the wall, approved I facilities for emergency lighting in the event of a power failure and an approved operating table capable of placing the patient at least in the Trendelenburg position and, where applicable, in other positions as well, depending on the operations to be carried out.
  - (8) The operating-theatre shall be provided with suitable suction apparatus (for use by the surgeon and the anaesthetist separately) with at least two suction points capable of effectively removing blood and mucus simultaneously. Provision shall also be made for emergency facilities of this kind, which can be used if the apparatus that is normally used fails.
  - (9) The operating-theatre shall be provided with suitable piping for conducting oxygen and nitrous oxide from a gas bank, unless such gases are supplied in cylinders- A Boyle's apparatus or other suitable type of anaesthetic apparatus with all the necessary connections for the patient's airways shall be provided A



- gas scavenging apparatus shall be mandatory.
- (10) The sterilising room shall have a floor area of not less than  $9\text{m}^2$  and a minimum wall length of 3m. Save that where an unattached operating-theatre unit was conducted on the same premises prior to the promulgation of these regulations and a sterilising room with a smaller floor area was used for this purpose, such room may continue to be so used.
- (11) The instruments, basins, dressings, dressing drums/packs, containers, water, etc., shall be sterilised in the sterilising room in an approved sterilising apparatus which may use one or more of the following methods:
- (i) Steam under pressure;
  - (ii) boiling water;
  - (iii) dry heat;
  - (iv) a sterilising gas;
  - (v) any other approved method:
- Provided that if a steam autoclave is used, the apparatus shall be mounted in an adequately ventilated machine room outside but immediately next to the sterilising room, with the autoclave facing into the sterilising room: Provided further that if the process used involves the production of steam, water vapour or other gases, a suitable apparatus for the effective removal thereof shall be provided.
- (12) Instead of built-in sterilising apparatus, suitable arrangements may be made for an approved central sterile supply department to provide sufficient sterile dressings, towels, bowls, basins, instruments, syringes and sterile water for all operations.
- (13) (1) The recovery room or area shall be in the demarcated area and shall have a floor area of not less than  $12\text{m}^2$  and a minimum wall length of 3m. It shall be fitted with at least one wash-hand basin to which hot and cold water shall be laid on to elbow-operated taps over the wash-hand basin; at least one flashproof wall plug; a portable lamp that can be taken to every bed; a suction apparatus which can effectively draw off blood and mucus and can reach every bed; a supply of oxygen so laid on that oxygen can be supplied to every bed; and suitable resuscitation apparatus. In addition, facilities shall be provided for the screening-off of patients if necessary.
- (2) A slop hopper and sink shall be provided in a suitable area.
- (14) The change room shall have a floor area of not less than  $7\text{m}^2$  and a minimum wall length of 2,1m and shall be fitted with flashproof wall plugs and at least one wash-hand basin to which hot and cold water is laid on. Flush toilets shall be provided in each change room on the basis of one for every eight persons, and such flush toilets shall be partitioned off from the rest of the change room. Such change room shall have adequate facilities where clothes and clean and soiled theatre clothing may be kept separately. Such change room shall have one door which opens inside the demarcated area and a separate entrance from outside the demarcated area.
- (15) The ward shall have a floor area of not less than  $8\text{m}^2$  for every bed. It shall be fitted with at least one flashproof wall plug and a wash-hand basin to which hot and cold water is laid on to elbow-operated taps.
- (16) The sluice room shall have a floor area of not less than  $5\text{m}^2$  and a minimum wall length of 2,1m. Sufficient cold water shall be laid on to a sluice pan. The sluice room shall be fitted with suitable shelves of impervious material for clean and disinfected bed pans and urine containers, as well as receptacles of impervious

- material, with tight-fitting lids, for soiled linen.
- (17) (i) The storage area for flammable material shall have a floor covered with a washable, impervious material;
- (ii) a suitable linen room or cupboard for clean linen shall be provided; and
- (iii) facilities for sterile storage shall be provided.
- (18) The duty room shall have a floor area of not less than 10m<sup>2</sup> and a minimum wall length of 2,4 m. It shall be next to the recovery room or area and between the latter and the ward, if any, with a window in the wall between the duty room and the recovery room or area and one in the wall between the duty room and the ward. It shall be equipped with hot and cold water laid on to elbow-operated taps over a wash-hand basin and a table with a top of impervious material, a refrigerator, and, unless provided elsewhere in the building, a flush toilet and sufficient shelves and lockers for keeping clothes, shoes and soiled gowns separately: Provided that instead of a duty room, a duty station may be provided for the nurse within the recovery room or area or the ward, and such station shall be equipped with such facilities as may be necessary for this purpose. An alarm system shall be installed to alert all staff of any emergency cases.

### **Furniture and equipment**

24. (1) In accommodation in which an unattached operating-theatre unit is being conducted the following facilities shall be provided in addition to the furniture and equipment:
- (i) Facilities for the administration of intravenous fluids and blood;
- (ii) sphygmomanometers;
- (iii) a stethoscope;
- (iv) syringes and needles;
- (v) a separate lockable cupboard for Schedule 7 substances;
- (vi) a separate lockable cupboard for all other Schedule 1-6 unscheduled medicines;
- (vii) a separate lockable cupboard for hazardous substances;
- (viii) an instrument cupboard for the operating-theatre.
- (2) In addition the operating-theatre unit shall contain sufficient suitable apparatus and instruments, including not less than two laryngoscopes. McGill forceps for adults and children, suitable endotracheal tubes with the necessary connections, tongue forceps, airways, a tracheostomy set, a cardiac massage set and defibrillator, as well as means to ventilate the patient if the oxygen supply fails, and other equipment and materials that may be required for emergencies.

### **Duties of proprietor**

25. The proprietor shall ensure that-
- (1) the accommodation in which he conducts his unattached operating-theatre unit is always in a clean and tidy condition;
- (2) all equipment and instruments are always clean and in good and safe working order, and are kept tidily in the appropriate storage place or cupboard when not in use;
- (3) any sterilising apparatus or equipment is not used or permitted to be used for any other purpose than sterilisation and that it is regularly tested for effectiveness and the results recorded in a register which he shall maintain for this purpose;

- (4) the operating-theatre is not used or permitted used for other purpose than as an operating-theatre;
- (5) a register is kept of all surgical operations performed and all specimens forwarded for pathological examination;
- (6) any scheduled substance in terms of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) and any hazardous substance in terms of the Hazardous Substances Act, 1973 (Act 15 of 1973), shall be stored only in lockable cupboards kept for the purpose;
- (7) no curtains are hung in the operating-theatre or the sterilising room;
- (8) no carpets or any loose covering materials are on or are laid on the floor of the operating-theatre or the sterilising room or any ward or duty room or patient area; that there is no wall paper against the walk of patient or treatment areas and further that all walls are kept free from affixed notices and paper or similar material which impedes cleaning;
- (9) any room showing dampness in the walls, floor or ceiling is not used for patient accommodation;
- (10) instruments and equipment shall at all times be kept clean, tidy and in good and safe working condition and, if used in the treatment of patients, shall be effectively disinfected or sterilised, as may be required, prior to use;
- (11) while there is a patient in the operating-theatre unit, no doors affording admission to the unit are locked;
- (12) the sluice room is not used or permitted to be used for any purpose other than the storage and cleansing of bed pans, urine bottles and similar containers, and the rinsing and depositing of soiled linen, dressings and other waste, until their removal, and that no place other than the sluice room is used for the storage and cleansing of such items;
- (13) in each sluice room proper receptacles of impervious material, having tight-fitting lids, are always available for soiled linen, dressings and other waste;
- (14) the contents of receptacles for soiled dressings and waste tissues are removed at least twice a day and effectively disposed of;
- (15) after use, all bed pans and urine containers are immediately emptied, rinsed clean and then disinfected;
- (16) an adequate number of refuse receptacles of impervious material, with tight-fitting lids in good condition, are available; that they are never left open; that the contents of such containers are effectively disposed of at least once daily, without causing a nuisance, and that such containers are properly washed and disinfected after they have been emptied;
- (17) the floors of the rooms used for the unattached operating-theatre unit are cleaned at least once a day and that all refuse is emptied into refuse receptacles;
- (18) in the event of the floors not being antistatic, an appropriate warning is prominently displayed;
- (19) requisites such as soap, a suitable nail brush and hand drying facilities are always available at every wash-hand basin in the unattached operating theatre unit;
- (20) A registered nurse or medical practitioner or dentist (apart from the registered nurses, medical practitioners or dentists in the operating-theatre) is always present as long as there is a patient not fully conscious in the recovery room or area;
- (21) whenever there is a bed patient on the premises of an unattached operating-theatre unit the services of at least an enrolled nurse is readily available;
- (22) the various rooms or areas are used only for the purposes for which they have been approved;

- (23) all services and measures generally necessary for adequate care and safety of patients are maintained and observed;
  - (24) aseptic principles are fully observed in the treatment of patients;
  - (25) all wash-hand basins for patients, staff and visitors are satisfactorily provided with cleansing materials and drying facilities;
  - (26) effective pest control is exercised;
  - (27) sewerage and storm-water drainage systems are maintained in conformity with the requirements of the local authority concerned;
  - (28) foodstuffs are bandied, kept, stored and prepared on the premises in conformity with public health standards and the regulations of the local authority concerned;
  - (29) adequate stand-by facilities for lighting and for the maintenance of vital equipment and services are provided and maintained;
  - (30) no unauthorised person has access to patient records and that the privacy and interests of patients are safeguarded;
  - (31) a "No Entry" sign is affixed to the operating-theatre unit; and
  - (32) a copy of these regulations, in a legible condition and up to date, is kept available on the premises.
26. The proprietor shall keep or cause to be kept in the following separate registers, where applicable:
- (a) A register of general medical and surgical patients admitted, substantially in the form of Annexure D;
  - (b) a register of maternity patients admitted and of deliveries substantially in the form of Annexure E;
  - (c) a register of all patients treated in any operating-theatre, substantially in the form of Annexure F;
  - (d) a register of out-patients or casualty patients treated., substantially in the form of Annexure G;
  - (e) a register, as required by the Secretary, of patients with infectious diseases, or any other special class of patient; and
  - (f) a register of the nursing staff, substantially in the form of Annexure H:
27. No proprietor shall admit to or treat in or allow to be admitted to or treated in any private hospital more patients than the number authorised by the certificate of registration. The Head of Department may give permission for more patients to be admitted or treated in emergencies or if he is satisfied that no other hospital facilities are available.
28. Every proprietor shall within 15 days of the end of each month furnish or cause to be furnished to the Secretary a return showing the number of patients exceeding daily during the month the number authorised for by the certificate of registration and the reasons such excess in each case.
29. Every proprietor shall without delay furnish to the Head of Department such returns and information as the Head of Department may from time to time require in relation to the control and management of the private hospital concerned, the facilities, stores or staff at its disposal, the services rendered therein and the patients receiving treatment or nursing care therein.

### **Private hospitals**

30. *Accommodation and facilities.*

A private hospital shall be conducted on premises where adequate and satisfactory provision has been made for -

- (a) one or more nursing units, including-
  - (i) beds in wards or rooms for the treatment of patients;
  - (ii) a duty room or duty station for nurses so placed that physical access to any patient requiring care is not impeded or delayed;
  - (iii) bathing and toilet facilities for patients;
  - (iv) a treatment or dressing room;
  - (v) separate storage space for linen, pharmaceuticals, ward equipment, patients' belongings and such sundry items as may be necessary for the management of the nursing unit;
  - (vi) a sluice room;
  - (vii) facilities for the cleansing and storage of cleaning equipment and materials;
  - (viii) a ward kitchen; and
  - (ix) connecting corridors;
- (b) a room or rooms, adequate for administrative control, enquiries, admission of patients and storage of records, which shall be separate from the duty room of a nursing unit and accessible to the staff without their having to pass through the patient areas;
- (c) a main kitchen;
- (d) store-rooms for bulk storage;
- (e) a rest-room and toilet facilities for staff;
- (f) a waiting area and toilet facilities for visitors;
- (g) sterile supplies;
- (h) facilities for the immediate supply of all necessary pharmaceutical products;
- (i) a laundry or a supply of clean linen;
- (j) a mortuary or for the immediate removal of any dead body; and
- (k) an approved incinerator or other suitable system for the effective and innocuous disposal of soiled dressings and surgically removed tissues.

31. ***Additional facilities***

Depending on the requirements of the patients admitted or treated at such hospital, any or all of the following facilities may be provided, in accordance with these regulations, and where deemed indispensable or required by the Head of Department, shall be thus provided:

- (a) An operating-theatre unit;
- (b) a separate maternity unit;
- (c) reception and treatment facilities for out-patients and/or casualties;
- (d) central sterilising facilities;
- (e) accommodation and facilities for employees;
- (f) facilities for-
  - (i) radiology and allied diagnostic purposes;
  - (ii) physiotherapy;
  - (iii) occupational therapy;
  - (iv) electro-convulsive treatment;
  - (v) psychotherapy;
  - (vi) any special investigation or treatment;
  - (vii) the training of nurses, medical practitioners and members of supplemen-

- tary health service professions;
- (viii) the medical examination of employees;
- (ix) the training of employees in first aid;
- (g) any other approved facilities.

32. ***General structural requirements***

Save where otherwise required in these regulations, the following structural requirements shall apply to all private hospitals:

- (1) The walls of the operating-theatre unit and of the labour unit shall be not less than 2,6 m high, measured from the floor to the ceiling and constructed of approved impervious material.
- (2) In the operating-theatre unit, the labour unit, all toilets, bathrooms and sluice rooms, and wherever else necessary, the joint between the floor and the walls shall be so rounded as to permit effective cleaning.
- (3) Each corridor or passageway used for patients shall be not less than 2 m wide and where patients are moved within the operating-theatre unit or labour unit the corridor shall be at least 2,5 m wide.
- (4) All rooms shall be satisfactorily lighted and ventilated.
- (5) Dustproof ceilings of smooth, impervious material, painted with a white or light-coloured suitable washable paint, shall be provided throughout all patient accommodation and treatment areas.
- (6) The floors of all rooms and corridors shall be of concrete or a similar impervious material brought to a smooth finish and, except where otherwise provided in these regulations, covered with a washable, impervious material.
- (7) All interior wall surfaces shall be given a smooth, hard plaster finish with rounded corners, painted with a light-coloured durable washable paint or alternatively satisfactorily covered with a similar washable, impervious material: Provided that, where walls have been painted, the walls behind wash-hand basins shall be specially clad to a height of at least 500 mm above, and to a distance of at least 500 mm beyond the sides of such wash-hand basins in glazed tiling or a special washable, impervious material so as to form an impervious finish continuous with the paintwork.
- (8) Effectively placed and adequate fire-hydrants, fire-hoses, fire-extinguishers, fire-escapes and emergency exits shall be provided and satisfactorily maintained.
- (9) Wash-hand basins shall be provided in the immediate vicinity of all toilets, urinals and sluices.
- (10) An airconditioning system shall be installed in the room provided for the storage of medicine in order to ensure a constant room temperature.

33. ***Patient accommodation.***

- (1) In this regulation any fixture shall, for purposes of determining minimum measurements, be regarded as a wall or part of a wall of a room in which a patient is accommodated.
- (2) No patient shall be accommodated in any room with a floor area of less than 10m<sup>2</sup> or in a single room where there is not a minimum space of -
  - (a) 0,9 m between any side of any bed and the nearest wall on that side; and
  - (b) 1,2m between the foot of any bed and the opposite wall.

- (3) No patient shall be accommodated in a room with more than one bed unless provision is made for a minimum space of -
  - (a) 0,75m between any side of any bed and the nearest wall;
  - (b) 0,9m between the sides of any adjacent beds; and
  - (c) 1,2m between the foot of any bed and the opposite wall or a minimum of 1,5 m between the foot of *any* bed and the opposite bed.
- (4) No infant shall be accommodated in a nursery unless there is a minimum space of-
  - (a) 0,75m between adjacent cots;
  - (b) 0,6 m between any side of any cot and the nearest wall; and
  - (c) 0,9 m between the foot of any cot and the opposite wall.
- (5) No patient room shall be used for the accommodation of both male and female patients, except when all patients are children not older than 10 years: Provided that a patient room may be used for the simultaneous accommodation of a husband and wife.
- (6) Except in the case of a mother and child, children and adults, shall always be accommodated in separate rooms: Provided that, where separate accommodation for adults and children under the age of 10 years is impractical for reasons of treatment, proper screening facilities shall be available.

#### 34. *Patient rooms*

- (1) Each patient room in a private hospital shall communicate directly with a corridor or passageway.
- (2) Doors giving access to rooms in which patients are or are to be accommodated shall be at least 1,2m wide.
- (3) Each patient room shall be provided with a wash-hand basin fitted with elbow-operated taps to which hot and cold water is laid on.
- (4) Each patient room shall be identified by displaying at the entrance -
  - (a) the number of the patient room; and
  - (b) the approved number of beds in such room.

#### 35. *Ancillary facilities*

- (1) (a) Where several patient rooms share toilet facilities or where a patient room with its own facilities contains more than eight beds, the following shall be provided:
  - (i) At least one bath or shower per 12 patients or part of such number: Provided that the proportion of baths to showers shall correspond to the function of the nursing unit;
  - (ii) at least one toilet per eight patients or part of such number, but in male wards a urinal may be substituted for every third toilet; and
  - (iii) at least one wash-hand basin per eight patients or part of such number.
- (b) Adequate special bathing facilities for babies shall be provided in direct

conjunction with nurseries.

- (2) (a) The size and equipment of the ward kitchen shall be adequate for the size and function of the nursing unit and for the system of supplying food.
- (b) The ward kitchen shall be so placed that it does not cause a nuisance.
- (3) (a) Depending on the system of supplying food, adequate provision shall be made for-
  - (i) facilities for taking delivery of, storing and preparing hot and cold food, and serving such food to patients and staff;
  - (ii) facilities for the removal, washing-up and storage of crockery and cutlery; and
  - (iii) facilities for the effective extraction of steam, smoke, vapour and heat.
- (b) Adequate and suitable provisions shall be made for-
  - (i) garbage bins which can be properly emptied and cleaned and which are provided with closefitting lids; and
  - (ii) wash-band basins for kitchen staff.
- (4) Suitable, change room, rest room and toilet facilities for employees shall be provided and such facilities shall be of the standard laid down in the Factories, Machinery and Building Work Act, 1941 (Act 22 of 1941), as amended.
- (5) Suitable and adequate waiting rooms, toilets and wash-hand basins shall be provided for visitors.

### **Operating-theatre unit in a private hospital**

#### **36. *General requirements.***

An operating-theatre unit shall include the follow

- (a) One or more operating-theatres with access only through a room, area, passageway or corridor which is clearly within the demarcated area and so planned and equipped that adequate control can be exercised over all persons and materials which enter such room, area, passageway or corridor;
- (b) and further within the demarcated area -
  - (i) adequate sterile pack and setting rooms;
  - (ii) a scrubbing-up area outside but adjacent to the operating-theatre, with satisfactory access to such operating-theatre: Provided that, subject to the recommendation of the Director with regard to any special services offered in the operating-theatre, the Head of Department may permit such scrubbing-up area to be situated within the operating-theatre;
  - (iii) a recovery room or area where patients can be adequately accommodated for post-operative nursing surveillance, which is immediately accessible to a medical practitioner and which has sufficient resuscitation and emergency facilities;
  - (iv) a sterile supply unit: Provided that a portion of the facilities of such unit may be screened off so as to fall outside the demarcated area;
  - (v) a sluice room to serve the operating-theatre or operating-theatres only: Provided that, where a special corridor is provided from which cleaning of the operating-theatre or operating-theatres can be effected such sluice



- room shall not be situated within the demarcated area, but shall be so situated as to have an access door from such corridor only;
- (vi) suitable change-room facilities, with direct access to the demarcated area, for medical practitioners, nursing and domestic staff: Provided that additional change facilities shall be provided for patients not utilising ward accommodation;
  - (vii) a transfer area, for the transfer of patients from ward trolleys to theatre trolleys, across the demarcated area;
  - (viii) a nurses' duty room or duty station which is so situated, constructed and equipped that it is possible for the nursing staff to observe patients directly and render assistance to patients where necessary;
  - (ix) if light refreshments are to be served, suitable facilities for storing, preparing and serving such refreshments;
  - (x) cleaners' facilities: and
  - (xi) separate store-rooms, or sufficient suitable storage cupboards in lieu thereof, for the storage of clean linen, medicines, equipment and sundry items.

### 37. *Dimensions*

Any operating-theatre shall have-

- (a) a floor area of not less than 30m<sup>2</sup>;
- (b) a wall height of not less than 3m;
- (c) a width of not less than 5,1m; and
- (d) an instrument setting area immediately off the operating-theatre.

### 38. *Floor*

- (1) The floor of any operating-theatre shall be of impervious material, laid without open interstices and with jointing filled in so as to provide a continuous impervious covering, and so finished that the wall covering and the floor covering are joined in a continuous smooth surface without interstices.
- (2) In an operating-theatre, unless anti-static flooring has been laid and maintained in conformity with the specifications of the South African Bureau of Standards, there shall be affixed and prominently displayed at the entrance to such theatre a cautionary notice to the effect that the floor of such theatre is not anti-static and that explosive anaesthetic agents, gases or cleaning agents are not to be used inside such theatre.

### 39. *Installations.*

At every theatre there shall be provided-

- (a) an adequate piped gas supply of oxygen and nitrous oxide;
- (b) an adequate lighting system;
- (c) an air-conditioning system fitted with filters effective for five micron particles and with sufficient capacity to maintain a temperature of at least 10°C and a relative humidity of at least 45 per cent;
- (d) an adequate and satisfactory mechanical suction system with at least two suction points;
- (e) adequate facilities for an emergency supply of oxygen and nitrous oxide,

emergency lighting and. emergency suction in the event of mechanical, electrical or other failure during an operation;

- (f) electric power to at least three flash-proof wall plugs with an earth leakage device at a minimum height of 1,5 m;
- (g) an approved operating table on which the patient can be positioned according to the requirements of the operation to be performed.

40. ***Corridors within operating-theatre units***

An unobstructed width of not less than 2,5m shall be maintained for patient trolleys in corridors and passageways within any operating-theatre unit.

41. ***Scrubbing-up areas within operating-theatre units***

- (1) Any scrubbing-up area shall have a width of not less than 2,1m and shall be so equipped as to permit both unhindered and simultaneous scrubbing-up by at least two persons under hot and cold running water from elbow-operating taps over splash-limiting basins or a drainage trough, and gowning prior to entering the operating-theatre.
- (2) Where the use of the operating-theatre is limited to the procedures listed in Annexure A, satisfactory provision for simultaneous separate scrubbing-up, by two persons only will be deemed sufficient for the purposes of this regulation.

42. ***Recovery areas within operating-theatre units***

- (1) The recovery room or area shall be inside the demarcated area and shall have a floor area of not less than 12m<sup>2</sup> and a wall length of not less than 3m, and shall provide sufficient space for at least one patient from each operating-theatre which it serves, calculated on the basis of 9m<sup>2</sup> of unobstructed floor area per patient.
- (2) The recovery room or area shall be fitted with -
  - (a) a wash-hand basin to which hot and cold water is laid on to elbow-operated taps;
  - (b) a sufficient supply of oxygen for each patient to be accommodated;
  - (c) a sufficiently adjustable fixed or portable lamp for every recovery bed or trolley;
  - (d) an adequate and satisfactory mechanical suction system with one suction point for every recovery bed or trolley;
  - (e) two flash-proof electric power outlets for every recovery bed or trolley; and
  - (f) facilities for screening off patients.

43. ***Sterile supply unit***

- (1) The sterile supply unit shall have a floor area of not less than 12m<sup>2</sup>, a wall length of not less than 3m and adequate free floor space.
- (2) The sterile supply unit shall be adequately equipped separately to receive, clean, pack, sterile and store instruments, materials, dressings, basins, containers, water

and sundry items used in connection with the treatment provided.

- (3) If a steam autoclave is used, it shall be mounted in an adequately ventilated and accessible machine room outside and immediately adjacent to the sterilising area, with the autoclave opening into such area: Provided that, if any sterilising process used involves the production of steam, water vapour or any other gases, a suitable means for the effective removal thereof shall be provided.
- (4) The provisions of this regulation shall not preclude any proprietor from establishing and maintaining, with the consent of the Head of Department, and subject to such conditions as the Head of Department may impose, an approved central sterile supply department in order to provide adequate sterile supplies to all patient accommodation and treatment areas of the hospital.

44. ***Duty rooms within operating-theatre units***

- (1) The theatre duty room shall have a floor area of not less than 10m<sup>2</sup> and a minimum wall length of 2,4m and shall be so situated and constructed as to make effective patient surveillance possible: Provided that an adequate duty station may be provided instead of a duty room.
- (2) The theatre duty room or station shall be equipped with such facilities as may be necessary for the purpose for which such theatre duty room or station is used.

45. ***Sluice rooms of operating-theatre units***

A theatre sluice room shall have a floor area of not less than 5m<sup>2</sup> and a minimum wall length of 2,1m and shall be fitted with -

- (a) a sluice pan;
- (b) adequate shelving for storing clean containers;
- (c) a stainless steel wash-up basin with hot and cold water; and
- (d) a wash-hand basin with hot and cold water.

46. ***Change rooms of operating-theatre units***

A theatre change room shall be of adequate size and shall have a floor area of not less than 9 m<sup>2</sup> and a minimum wall length of 2,1 m and shall be provided with -

- (a) a wash-hand basin to which hot and cold water is laid on;
- (b) suitably partitioned off toilets on the basis of one toilet for every seven members of the theatre staff or part of such number;
- (c) adequate facilities for the separate storage of personal clothing and effects, clean and used theatre clothing; and
- (d) a shower cubicle with a dry change area.

**Maternity unit**

47. ***General requirements***

A maternity unit shall include -

- (a) one or more nursing units, in accordance with these regulations;
- (b) adequate nursery facilities which shall include -
  - (1) a separate room where facilities for special care shall be provided, including-
    - (i) at least one incubator;
    - (ii) resuscitation equipment with suction and oxygen; and
    - (iii) oxygen and suction supply in the: main nursery;
  - (2) resuscitation equipment in the delivery room shall include-
    - (i) a table of a suitable height; with
    - (ii) overhead heating; and
    - (iii) oxygen and suction supply;
- (c) a milk kitchen, if more than 15 mother beds are provided;
- (d) a patients' preparation room, if more than 15 mother beds are provided;
- (e) a labour unit consisting of-
  - (i) a delivery room or rooms on the basis of one delivery room for every 10 mother beds. or one delivery room plus a room for patients in the first stage of labour for every 15 mother beds;
  - (ii) ancillary services, including-
    - (aa) a sluice room with provision for storing, examining and disposing of placentas; and
    - (bb) separate storage facilities for sterile packs and instruments, linen, medicines and sundry equipment;
- (f) where more than 15 mother beds are provided and no operating-theatre facilities are readily available, provision shall be made for an operating-theatre unit with sufficient suitable theatre facilities.

#### 48. *Delivery rooms*

- (1) Each delivery room shall have a floor area of not less than 16m<sup>2</sup> and a minimum width of 3,7 m.
- (2) Each delivery room shall also contain -
  - (a) adequate scrubbing-up facilities;
  - (b) a suitable adjustable lamp, fixed or mobile;
  - (c) an anti-static floor if explosive anaesthetic gases are used;
  - (d) adequate provision for oxygen; and
  - (e) adequate baby resuscitation facilities.

#### **Alterations**

- 49. No building of any private hospital or unattached operating-theatre unit or any portion of such building shall be extended, demolished or otherwise structurally or functionally altered without the written approval of the Head of Department. Any proprietor wishing to obtain such approval shall apply in writing and every such application shall -
  - (1) be accompanied by detailed plans and specifications; and
  - (2) set out in full the reasons for the proposed extension, demolition or alteration.

#### **Displaying of certificate of registration at private hospitals and unattached operating-theatre units**

- 50. The holder of a valid certificate of registration shall display or cause to be displayed in a

conspicuous place on the premises to which such certificate relates, the certificate of registration mentioned in regulation 14(1) or 14(3).

### **Inspections**

51. The Head of Department may at any time, and as often as he may deem necessary, inspect or have inspected by an inspecting officer any private hospital or unattached operating-theatre unit.
52. The proprietor of a private hospital or unattached operating-theatre unit or any other person responsible for the management or control thereof or who is in charge of the nursing services thereof shall render to the inspecting officer in terms of these regulations all information the said officer may require in regard to the organisation and management of such private hospital or unattached operating-theatre unit and the accommodation, nursing and treatment of the patients. All registers, clinical records and any other records in connection with patients and staff shall also be available for inspection.
53. No person shall in any way obstruct any inspecting officer carrying out his inspection or refuse to furnish to the best of his knowledge any information requested by such officer or to show any apparatus or place or thing or to unlock any cupboard.
54. The Head of Department may at any time direct the proprietor of such private hospital or unattached operating-theatre unit by notice in writing to effect, within a reasonable period stated in the notice, such structural alterations or such improvements in regard to the organisation or management of the said private hospital or unattached operating-theatre unit or to acquire or replace such equipment or to remedy such defects as may be specified in the said notice.

### **Appeals**

55. The proprietor or prospective proprietor of a private hospital or unattached operating-theatre unit may appeal in writing to the Minister against any decision made by the Head of Department in terms of any provision of these regulations in respect of such proprietor or prospective proprietor, as the case may be, of a private hospital or unattached operating-theatre unit.
56. An appeal in terms of regulation 55 shall be lodged within seven days of the decision appealed against having come to the knowledge of the proprietor or prospective proprietor, as the case may be, and shall clearly state-
  - (1) against which decision such appeal is lodged; and
  - (2) the grounds on which such appeal is lodged.
57. Any appeal in terms of these regulations shall be lodged with the Head of Department, who shall submit it to the Minister together with his reasons for the decision against which the appeal is being lodged.
58. The Minister may confirm, amend or revoke a decision taken by the Head of Department in terms of the provisions of these regulations and inform the owner or prospective owner of a private hospital or unattached operating-theatre unit in writing of his decision.

## Offences and penalties

59. Any person who -
- (1) establishes, extends, conducts, maintains, manages, controls or renders a service in any private hospital or unattached operating-theatre unit which is not registered in terms of the provisions of these regulations; or
  - (2) extends, demolishes or makes structural alterations to the existing buildings of a private hospital or unattached operating-theatre unit, or any portion of such buildings or alters the purpose for which such buildings are used, without the prior approval in writing of the Head of Department; or
  - (3) is the proprietor of or is employed at a private hospital or unattached operating-theatre unit and who-
    - (i) fails or refuses to allow the Head of Department, or any person acting on his behalf, access to such hospital or unit for the purpose of an inspection in terms of regulation 52; or
    - (ii) fails to comply with the provisions of regulation 54; or
    - (iii) obstructs or hinders the Head of Department or any person acting on his behalf in the performance of his duties in terms of regulation 53, or who contravenes or fails to comply with such provisions,
 shall be guilty of an offence and liable-
    - (a) upon a first conviction, to a fine not exceeding R500 or to a term of imprisonment not exceeding six months or to both such fine and such term of imprisonment;
    - (b) upon a second conviction for a similar offence, to a fine not exceeding R1 000 or to a term of imprisonment not exceeding one year or to both such fine and such term of imprisonment; and
    - (e) upon a third or subsequent conviction for a similar offence, to a fine not exceeding R1 500 or to a term of imprisonment not exceeding two years or to both such fine and such term of imprisonment.
60. All provincial-aided hospitals are excluded from these regulations.

## 61. *Forms*

Forms essentially as specified in the annexures hereto shall be used for the purposes of the Health Act, 1977 (Act 63 of 1977), and the regulations made under the Act.

## Repeal of regulation R. 1071 of 25 June 1971

62. (1) The provisions of the regulations in respect of unattached operating-theatre units (Regulation R. 1071 of 25 June 1971), are hereby repealed in so far as they apply or relate to unattached operating-theatre units.
- (2) Any notice, order, decision, approval, permission, authority, information or document issued, made, granted or furnished and any other action taken under any provision of these regulations or repealed by these regulations shall, if not inconsistent with the provisions of these regulations, be deemed to have been issued, made, granted, furnished or taken under the corresponding provisions of these regulations.

63. Date of commencement of regulations is 1 April 1980.

### ANNEXURES

Annexure	Form	Subject
A.....	-	Scope of prescribed procedures carried out in unattached operating-theatre units
B.....	I	Application for registration as a private hospital/unattached operating-theatre unit
C.....	II	Certificate for registration
D.....	III	Register of patients admitted
E.....	IV	Maternity register
F.....	V	Operating-theatre register
G.....	VI	Casualty and out-patient register
H.....	VII	Register of nursing staff

### ANNEXURE A

#### SCOPE OF PRESCRIBED PROCEDURES CARRIED OUT IN UNATTACHED OPERATING-THEATRE UNITS

In unattached operating-theatre units no prescribed procedures shall be carried out unless the necessary facilities, equipment and assistance are available for such procedures for resuscitation and for post-operative care.

#### A. Dentistry

- (1) Restorative dentistry.
- (2) Removal of teeth.
- (3) Minor oral procedures.

#### B. General surgery

- (1) Warts.
- (2) Circumcision.
- (3) Stitching of wounds and tendons.
- (4) Incision of superficial abscesses.
- (5) Evacuation of haematoma.
- (6) Removal of finger-nails and toe-nails.
- (7) Removal of superficial foreign bodies, but only where methods for accurate localisation are available.
- (8) Sigmoidoscopy and colonoscopy.
- (9) Removal of simple superficial turnouts.
- (10) Injection of haemorrhoids and varicose veins.
- (11) Abdominal paracentesis.
- (12) Anal dilatations.
- (13) Muscle biopsy.
- (14) Evacuation of thrombosed external haemorrhoids.
- (15) Treatment of fissure *in ano*.
- (16) Lateral sphincterotomy.

**C. Psychiatry**

- (1) Electroconvulsive therapy.
- (2) Narcoanalysis.
- (3) Electrostimulation.
- (4) Lumbar and cisternal puncture.

**D. Orthopaedics**

- (1) Reduction of simple fractures.
- (2) Reduction of simple dislocations.
- (3) Manipulations.
- (4) Aspiration of joints.
- (5) Injections into joints.
- (6) Arthrography.
- (7) Carpal-tunnel release.
- (8) Tendon suture.
- (9) Nerve suture.
- (10) Ganglion removal.

**E. Ear, nose and throat**

- (1) Laryngoscopy.
- (2) Proof puncture and sinus irrigation.
- (3) Paracentesis, including insertion of grommets and toilet of ears under general anaesthetic.
- (4) Cauterisation.
- (5) Removal of foreign bodies and polyps.
- (6) Reduction of fractured nose.
- (7) Tonsillectomy and adenoidectomy.

**F. Gynaecology and obstetrics**

- (1) Examination under anaesthetic,
- (2) Incision of Bartholin's cyst.
- (3) External version.
- (4) Insertion of intra-uterine contraceptive device.
- (5) Cauterisation of cervix.
- (6) Endometrial biopsy.
- (7) Hysterosalpingogram.
- (8) Excision of cervical polyp. Vulva biopsy.
- (10) Hormone implantation.
- (11) Hymenectomy.
- (12) Dilatation and curettage.
- (13) Diagnostic laparoscopy.
- (14) Sterilisation.
- (15) Shirodkar operation.
- (16) Investigative radiological procedures requiring general anaesthetics.
- (17) Other minor procedures which will not necessitate an X-ray within the unit within a period of 12 hours,



**G. Ophthalmology**

- (1) Examination of children under anaesthetic.
- (2) Removal of corneal foreign bodies.
- (3) Probing of tear ducts.
- (4) Incision of Meibomian cysts.
- (5) Removal of Pterygium.

**H. Dermatology**

- (1) Diathermy and curettage of warts.
- (2) Diathermy and curettage of plantar warts.
- (3) Diathermy and curettage of *verrucae acuminatae*.
- (4) Biopsy of skin or mucous membrane by means of incision or punch.
- (5) Removal of benign superficial lesions.
- (6) Removal of malignant superficial lesions.
- (7) Incision and drainage of superficial abscess.

**I. Urology**

- (1) Cystoscopy.
- (2) Urethral dilation.
- (3) Vasectomy.
- (4) Testis biopsy.
- (5) Meatotomy.
- (6) Circumcision.
- (7) Removal of urethral caruncles.
- (8) Removal of sperniatocele.

**J. Thoracic surgery**

- (1) Pleural aspiration and needle biopsy of pleura and lung.
- (2) Intercostal block.
- (3) Removal of superficial tumours.
- (4) Bronchoscopy with or without removal of foreign bodies
- (5) Qesophagoscopy with or without removal of foreign bo
- (6) Dilatation of oesophagus.

**K. Neurosurgery**

As under B. plus, where applicable:

- (1) Examination under an anaesthetic.
- (2) Lumbar puncture and similar procedures such as intrathecal phenol or alcohol administration, spinal root block, air encephalogram, myelogram, drug administration and spinal drainage,
- (3) Nerve block, e.g. Gasserian ganglion, occipital nerve, etc.
- (4) Angiography-needle or catheter.
- (5) Tracheotomy.
- (6) Drainage of ventricles through existing burr, hole or fontanelle or bone biopsy, for

purposes of drainage or administration of contrast media or drugs.

**L. Plastic surgery**

As under B, plus, where applicable:

- (1) Plastic repair of small wounds.
- (2) Manipulation of nasal fracture (under local anaesthetic).
- (3) Small skin transplants.
- (4) Excision and repair of scars (under local anaesthetic).

**M. Medicine**

- (1) Gastroscopy and duodenoscopy.
- (2) Signaoidoscopy.
- (3) Rectal biopsy.
- (4) Sternal puncture.
- (5) Diagnostic paracentesis of pleura and peritoneum.
- (6) Injection into nerve roots and ganglia.
- (7) Lumbar puncture.

**ANNEXURE B**

Form I

Department of Health

Application for registration as a \*private hospital/unattached operating-theatre unit in terms of Regulation R. 158 of I February 19 80.

The Secretary for Health  
Private 3ag X88  
PRETORIA  
0001

Application is hereby made for the registration of the following \*private hospital/unattached operating-theatre unit, details of which are supplied below for the year ending 31 December .....

- 1. Name of private hospital/unattached operating-theatre unit.....
- 2. Situation of premises (street, locality, town) .....
- 3. Name and postal address of registered owner of the property (premises) .....
- 4. Name and address of proprietor (in the case of a company or association, its nominee) who will be conducting the \*private hospital/unattached operating-theatre unit.....
- 5. Name and address of the medical practitioner or registered nurse and midwife who will be in charge .....
- 6. If a medical practitioner will be in charge, name and qualifications of the registered nurse and midwife who will be in charge of the nursing services.....
- 7. Name and allocation of beds available for patients (see notes below).....

.....

	General		Maternity		Infectious diseases	Others (specify)	Total
	Adults	Children	Mothers	Babies			
Whites.....							
Non-whites...							

8. Number of:
  - (a) Operating theatres.....
  - (b) Delivery rooms.....
9. Changes in the patient accommodation/beds available during the current year, if any (specify) .....
10. Numbers of registered staff \*employed at date of application/to be employed at date of new registration applied for:

		Practitioners		Nurses	
		Medical	Dental	Registered	Student
Full-time.....	White.....				
	Non-white.....				
Part-time.....	White.....				
	Non-white.....				

11. Number of full-time enrolled nurses \*employed at the date of application / to be employed at date of new registration applied for:

		Enrolled nurses	Enrolled student nurse	Entolled nursing assistants	Entolled pupil nursing assistants
		Full-time.....	White.....		
	Non-white...				

12. Other full-time registered staff employed (if any) (specify) .....
13. Other part-time registered staff employed (if any) (specify) .....
14. If the hospital is recognised by the South African Nursing Council as an approved training school for nurses, midwives or enrolled nurses or enrolled nursing assistants:
  - (a)

General nurses	Midwives	Enrolled nurses	Enrolled nursing assistants

- (b) If the hospital is recognised as an approved training school for one or more of the categories of nursing staff referred to in subsection (a), the following information should also be given:

Category	Number of registration or enrolment	Date of issue

	certificate issued by the S.A.N.C.	
(i) Student general nurses....		
(ii) Student midwives.....		
(iii) Pupil nurses.....		
(iv) Pupil nursing assistants...		

Registration with the SA Nursing Council (specify):

	Number of original certificate	Date of issue	Annual registration	
			Receipt number	Date
General.....				
Midwifery.....				
Other.....				

- (c) Other trained staff, excluding person in control:  
 (i) Registered nurses/midwives:

Name	Qualifications	Number of original certificate	Date of issue	Annual registration	
				Receipt number	Date

- (ii) Enrolled nurses .....  
 Total.....
- (iii) Enrolled nursing assistant.....  
 Total.....

15. Arrangements for the training and teaching of each of the following categories, as applicable:

- (i) Student nurses.....  
 (ii) Student midwives.....  
 (iii) Pupil nurses.....  
 (iv) Pupil nursing assistants.....

I hereby certify that the above particulars are true and correct

Place.....

Date.....

Signature of proprietor

N.B.-If available space is insufficient, attached separate schedule.

Notes:

- (a) \*Words designated by an asterisk to be deleted if not applicable  
 (b) This form is to be used for the first and every subsequent application for registration.  
 (c) Item 7: The numbers of beds, cribs/cots actually available for accommodating patients are to be stated, but these exclude -
- all trolleys;

- all waiting, preparation, first stage and labour room beds and cots in maternity units;
- the recovery trolleys and recovery beds of an operating-theatre unit of a private hospital, but not those of an unattached operating-theatre unit.

**ANNEXURE C**

Form II

Certificate No.....

Reference No.....

**DEPARTMENT OF HEALTH  
CERTIFICATE OF REGISTRATION**

It is hereby certified that the .....  
 .....  
 situated at .....  
 is registered as a \*private hospital/unattached operating-theatre unit in terms of Regulation R.158 of 1 February 1980 for a period of .....months, ending.....

Name of proprietor or managing body.....  
 Address of proprietor or managing body.....  
 .....  
 Name of person in charge.....  
 Maximum number of patients who may be accommodated at the same time:

Patients that can be accommodated simultaneously	Maximum number accommodated	
	White	Non-white
* Medical and surgical:		
(a) Adults.....		
(b) Children.....		
* Maternity:		
(a) Mothers.....		
(b) Babies.....		
Infectious diseases.....		
Other (specify).....		

With the exception of the above-mentioned activities, the activities of the above-mentioned \*private hospital/unattached operating-theatre unit are restricted as follows.....  
 .....

Signed at ..... this .....day  
 of .....19.....

.....  
 Head of Department

*This certificate is not transferable and must be renewed annually*

\* Delete if not applicable





**ANNEXURE E**

Form IV

**MATERNITY REGISTER**

Serial number of case.....  
Date admitted.....  
Name of patient.....  
Age.....  
Population group.....  
Address.....  
.....  
(a) Number of previous confinements.....  
(b) Number of previous miscarriages.....  
(c) Date of confinement.....  
(d) Date of miscarriage.....  
Full-term, premature or miscarriage? If miscarriage, state approximate number of months...  
.....  
Presentation.....  
Duration of labour.....  
Sex of infant.....  
Born alive or dead.....  
Complications (if any) during or after labour.....  
.....  
Name of medical practitioner (block letters) .....

Signature.....  
Name of midwife (if any) .....

Date of midwife's last visit or date of discharge.....  
Condition of mother then.....  
Remarks.....  
.....

Signature

**ANNEXURE F**

Form V

**OPERATING-THEATRE REGISTER**

Serial number .....

Date.....

Number.....

Admission register No. ....

Sex.....

Age.....

Ward.....

Anaesthetics.....

Name of anaesthetist.....

Name of surgeon.....



Name of assistant surgeon.....  
 Operation.....  
 Duration of operation: From..... to .....

Drains, etc .....

Theatre.....

Signature of nurse taking operation.....

Signature of co-checker.....

Remarks (complications, accidents, etc.) .....

.....

**ANNEXURE G**

Form VI

**CASUALTY AND OUT-PATIENT REGISTER**

Serial no.	Register no.	Date	Time	Name	Age	Sex	Address	Complaint or Injury	Discharge	Name of medical practitioners

**ANNEXURE H**

Form VII

**REGISTER OF NURSING STAFF**

Full name.....

Maiden name (if applicable) .....

Identity number .....

Sex ..... Date of birth .....

Population group ..... Nationality .....

<b>PROFESSIONAL QUALIFICATIONS</b>		
Degree/Diploma/Certificate	Registration certificate	
	Date	No.

Receipt of current registration/enrolment with SA Nursing Council:

Date .....

Number .....

Receipt of current membership of SA Nursing Association:

Date .....

Number .....

Date of appointment .....

Date of termination of service .....