Licensure of Out-patient Surgical Facilities

19-13-D56. Licensing of out-patient Surgical Facilities Operated by Corporations

(a) Definition.
   (1) For the purpose of section 19-13-D56, an out-patient surgical facility is defined as operated by a corporation other than a hospital which provides ambulatory Surgical care in addition to the provision of medical care for diagnosis and treatment of persons with acute or chronic conditions or to the provision of surgical care to well persons.
   (2) Ambulatory surgical care is defined as surgical care not requiring overnight stay but requiring a medical environment exceeding that normally found in a physician's office. This medical environment may include any or all of the following:
      (A) The pathological process for which the operation is to be performed shall be localized and not conducive to systemic disturbance.
      (B) The patient shall not, in the opinion of the attending physician, have other significant physiological, biochemical or psychiatric disturbance which might be worsened by the operation.
      (C) The preoperative work-up to be done following admission shall not be such as to extend the admission beyond the normal period of clinic operation during one day.
      (D) The postoperative recovery period anticipated shall not require skilled medical or nursing care such as to extend the admission beyond the normal period of clinic operation during one day.
      (E) Anesthesia requirement, which may render the patient unconscious and unable to walk, but which will not prohibit discharge during the normal period of clinic operation during the day on which the operation is performed.

(b) Physical Standards.
   A. Plans and specifications for new construction or alterations shall be submitted to the state department of health for review and approval before construction is undertaken.
   B. The commissioner of health has issued the following minimum requirements concerning the physical standards which will be the basis for review in the state department of health.
      (1) Code.
         (a) Every building where, on or after the effective date of these regulations, is constructed or converted for use, in whole or in part, as an out-patient surgical center shall comply with the requirements of the Basic Building Code, as prepared by the Public Works Department, State of Connecticut; except as such matters are otherwise provided for in a local municipal charter, or statutes, or in the rules and regulations authorized for promulgation under the provisions of the Basic Building Code.
         (b) In addition to the State of Connecticut Basic Building Code, all outpatient surgical facilities shall comply with the requirements of the following codes and standards:
            (1) State of Connecticut Fire Safety Code
            (2) NFPA-101 Life Safety Code
            (3) NFPA-76A Essential Electrical Systems for Health Care Facilities
            (4) NFPA-56A Inhalation Anesthetics
            (5) NFPA-56F Nonflammable Medical Gases
(6) NFPA-56G Inhalation Anesthetics in Ambulatory Care Facilities
(7) For reference purposes only-NFPA-76B-M Electricity in Patient Care Facilities
(8) The State of Connecticut labor laws, local fire safety codes and zoning ordinances. Only the most current code or standard shall be used.

(c) Facilities shall be available and accessible to the physically handicapped and designed in accordance with ANSI standards.
(d) An annual certificate from the local fire marshal that precautionary measures meet his approval shall be submitted with the annual application for licensure to the state department of health.

(2) Site. The site or location of a new surgical outpatient center shall be approved by the state department of health.

(3) Size and Design.
(a) The extent (number and types) of the diagnostic, clinical and administrative facilities to be provided will be determined by the services contemplated and estimated patient load.
(b) Prime consideration shall be given to patient traffic from the patient parking area to out-patient admissions and through the surgical department to discharge offices and to covered areas for patient pick-up.

(4) Privacy for Patient. The design of the facility shall provide for the privacy and dignity of the patient during interview, examination and treatment.

(5) Maintenance of Systems and Equipment. All electrical gas, fire and alarm systems and equipment shall be tested to standards initially prior to the placing in service and tested periodically thereafter. Permanent records shall be maintained.

C. Administrative Provisions. The following shall be provided:
(1) Entrance. At grade level or ramped and in multi-story structures where the unit is above street level, ready access to an elevator.
(2) Waiting Room. Public toilet facilities, drinking fountain, public telephone, and seating accommodations for long waiting periods shall be provided on the premises.
(3) General or Individual Offices. For medical records and administrative and professional staffs.
(4) Interview space(s) for private interviews relating to social services, credit and admissions.
(5) Special Storage. For employees', patients' personal effects.

D. Clinical Facilities. The following shall be provided:
(1) General Purpose Examination Room(s). For medical, obstetrical and similar examinations. Shall have a minimum floor area of eighty (80) square feet each, excluding such spaces as vestibule, toilet, closet and work counter (whether fixed or movable). A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.
(2) Treatment Room(s) for Minor Surgical Procedures and Cast Procedures. Shall have a minimum floor area of one hundred-twenty (120) square feet each, excluding such spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). The minimum room dimension shall be ten feet. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.
(3) Outpatient surgery change areas. A separate area shall be provided where out-patients change from street clothing into hospital gowns and are prepared for surgery. This would include a waiting room, lockers,
toilets, clothing change or gowning area, and space for the administration of medications.

(4) Laboratory. Any out-patient surgical center which carries out laboratory testing within the unit itself shall establish a separate room properly labeled as a laboratory. This room shall be capable of being closed off from the rest of the unit by a suitable door. This laboratory shall contain a work counter, storage cabinets and sink and other appropriate equipment and supplies.

(5) Operating Room(s). Each operating room shall have a minimum clear area of two hundred fifty (250) square feet exclusive of fixed and movable cabinets and shelves. Additional clear area may be required by the program to accommodate special functions in one or more of these rooms. Provide an emergency communication system connecting with the surgical suite control station. Provide at least one X-ray film illuminator in each room, oxygen and vacuum.

(6) Recovery Room(s). Room(s) for post-anesthesia recovery for outpatient surgical patients shall be provided and shall contain handwashing facilities, charting facilities, clinical sink with oxygen and vacuum available for each patient.

E. Surgical Service Areas. The following services shall be provided:

(1) Control station located to permit visual surveillance of all traffic which enters the operating suite.

(2) Supervisor's office or station (may be shared with the control station.)

(3) Sterilizing facility(ies) with high speed autoclave(s) conveniently located to serve all operating rooms. When the program indicates that adequate provisions have been made for replacement of sterile instruments during surgery, sterilizing facilities in the surgical suite will not be required.

(4) Scrub facilities. Two scrub stations shall be provided near entrance to each operating room; however, two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of each operating room. Provide viewing panels with wired glass to permit observation of the operating room from the scrub area.

(5) Soiled workroom for the exclusive use of the surgical suite staff. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, work counter, sink equipped for handwashing, waste receptacle, and linen receptacle.

(6) Clean workroom. A clean workroom is required when clean materials are assembled within the surgical suite prior to use. A clean workroom shall contain a work counter, sink equipped for handwashing, and space for clean and sterile supplies.

(7) Anesthesia Storage Facilities. A separate room shall be provided for the storage of flammable gases (in accordance with the requirements detailed in NFPA 56A) if such gases are used.

(8) Anesthesia workroom for cleaning, testing and storing anesthesia equipment. It shall contain a work counter and sink.

(9) Medical gas storage. Space for reserve storage of nitrous oxide and oxygen cylinders shall be provided and constructed of one hour fire resistive construction and in accordance with NFPA 56A and 56F.

(10) Equipment storage room(s) for equipment and supplies used in surgical suite.

(11) Staff clothing change area. Appropriate areas shall be provided for male and female personnel (orderlies, technicians, nurses and doctors) working within the surgical suite. The areas shall contain lockers, showers, toilets, lavatories equipped for handwashing, and space for donning scrub suits and boots. These areas shall be arranged to provide a one-way traffic pattern so that personnel entering from outside the
surgical suite can change, shower, gown, and move directly into the surgical suite. Space for removal of scrub suits and boots shall be designed so that personnel using it will avoid physical contact with clean personnel.

(12) Lounge and toilet facilities for surgical staff.
(13) Janitors’ closet. A closet containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided exclusively for the surgical suite.
(14) Doctors’ Dictation. This space should be private and adequate in size for the total number of doctors who may be dictating at the same time. It should be located adjacent to but not inside the nurses’ station, lounge or doctors’ dressing area.

F. Supporting Services.
(1) Janitors’ Closet(s). This room shall contain a floor receptor or service sink and storage for housekeeping supplies and equipment.
(2) Stretcher Storage Area. This area shall be out of direct line of traffic.
(3) Employees’ Facilities. Locker rooms, lounges, toilets, or shower facilities, as required, shall be provided to accommodate the needs of all personnel.
(4) Nourishment Rooms. Facilities and space should be provided for preparation of light nourishment, and refrigeration of juices. An ice machine is desirable. Handwashing facilities must be provided in the room; should be located near the recovery suite.
(5) General Storage Facilities. For office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

G. Details and Finishes. All details and finishes shall meet the following requirements:
(1) Details.
(a) Minimum public corridor width shall be five feet, zero inches (5’-0”). Patient transfer corridors shall be eight feet, zero inches (8’-0”) wide.
(b) Each building shall have at least two exits remote from each other. Other details relating to exits and fire safety shall be in accordance with the State Fire Safety Code.
(c) The minimum width of doors for patient access to examination and treatment rooms shall be three feet, zero inches (3’-0”); operating and recovery room doors shall be three feet, 10 inches (3’-10”) wide and seven feet, zero inches (7’-0”) high.
(d) Doors on all openings between corridors and rooms or spaces subject to occupancy, except elevator doors, shall be swing type.
(e) The location and arrangement of handwashing facilities shall permit their proper use and operation. Particular care shall be given to the clearances required for blade-type operating handles.
(f) Paper towel dispensers and soap dispensers shall be provided at all handwashing fixtures.
(g) Radiation protection requirements of X-ray and gamma ray installations shall conform with NCRP Reports Nos. 33 and 34. Provisions shall be made for testing the completed installation before use.
(h) All handwashing sinks used by medical and nursing staff shall be trimmed with valves which can be operated without the hands.
(i) If flammable gases are used, compliance with all requirements of NFPA 56A Inhalation Anesthetics is required for the installation
of conductive flooring, electrical systems, ventilation requirements and maintenance.

(j) Ceiling heights shall not be less than nine feet, six inches (9'-6") in operating rooms, and eight feet, zero inches (8'-0") in all other rooms and corridors.

H. Finishes.
(1) Flame spread and smoke developed ratings of finishes shall be Class "A" 0-25.
(2) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas frequently subject to wet cleaning methods; floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet, such as shower and bath areas and certain work areas, shall have a nonslip surface.
(3) Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.
(4) Wall bases in soiled workrooms and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor.
(5) Duct linings shall not be used in systems supplying operating rooms and recovery rooms.

I. Air Conditioning, Heating and Ventilating Systems.
(1) Temperatures and humidities.
(a) The systems shall be designed to provide the following temperatures and humidities in the areas noted:

<table>
<thead>
<tr>
<th>Area Designation</th>
<th>Temperature °F</th>
<th>Relative Humidity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Rooms</td>
<td>70-76</td>
<td>50 60</td>
</tr>
<tr>
<td>Recovery Rooms</td>
<td>70-76</td>
<td>50 60</td>
</tr>
</tbody>
</table>

(2) Ventilation system details. All air-supply and air-exhaust systems shall be located at the discharge end of the system. The ventilation rates shown in table 1 shall be considered as minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates.
(a) Outdoor intakes shall be located as far as practical but not less than twenty-five feet, zero inches (25'-0") from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents stacks, or from areas which may collect vehicular exhaust and other noxious fumes. The bottom of outdoor air intakes serving central systems shall be located as high as practical but not less than six feet, zero inches (6'-0") above ground level, or if installed above the roof, three feet, zero inches (3'-0") above the roof level.
(b) The ventilation systems shall be designed and balanced to provide the pressure relationship as shown in table No. 1.
### TABLE I - GENERAL PRESSURE RELATIONSHIPS AND VENTILATION OF CERTAIN OUT-PATIENT SURGICAL AREAS

<table>
<thead>
<tr>
<th>Area Designation</th>
<th>Pressure Relationship to Adjacent Areas</th>
<th>Minimum of Changes of Outdoor Air per Hour Supplied to Room</th>
<th>Minimum Total Air Changes per Hour Supplied to Room</th>
<th>All Air Exhausted Directly to Outdoors</th>
<th>Recirculated within Room Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Room</td>
<td>P</td>
<td>5</td>
<td>25</td>
<td>Optional</td>
<td>No</td>
</tr>
<tr>
<td>Examination &amp; Treatment Room</td>
<td>E</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Recovery Room</td>
<td>P</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>No</td>
</tr>
<tr>
<td>Examination Room</td>
<td>E</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Medication Room</td>
<td>P</td>
<td>2</td>
<td>4</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Treatment Room</td>
<td>E</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>No</td>
</tr>
<tr>
<td>X-ray</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy Room</td>
<td>N</td>
<td>2</td>
<td>6</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Treatment Room</td>
<td>E</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Soiled Workroom</td>
<td>N</td>
<td>2</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clean Workroom</td>
<td>P</td>
<td>2</td>
<td>4</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Darkroom</td>
<td>N</td>
<td>2</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Toilet Room</td>
<td>N</td>
<td>Optional</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bathroom</td>
<td>N</td>
<td>Optional</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Janitors’ closet</td>
<td>N</td>
<td>Optional</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterilizer Equipment Room</td>
<td>N</td>
<td>Optional</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Laboratory, General</td>
<td>N</td>
<td>2</td>
<td>6</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Anesthesia Storage (Flammable)</td>
<td>E</td>
<td>Optional</td>
<td>8</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Central Medical and Surgical Supply Soiled or Decontamination Room</td>
<td>N</td>
<td>2</td>
<td>6</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clean Workroom</td>
<td>P</td>
<td>2</td>
<td>4</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Unsterile Supply Storage</td>
<td>E</td>
<td>2</td>
<td>2</td>
<td>Optional</td>
<td>Optional</td>
</tr>
</tbody>
</table>

Legend:  P = Positive       E = Equal       N = Negative

(c) All air supplied to operating rooms, shall be delivered at or near the ceiling of the area served, and all exhaust air from the area shall be removed near flood level. At least two exhaust outlets shall be used in all operating and delivery rooms.

(d) Corridors shall not be used to supply air to or exhaust air from any room.

(e) All central ventilation or air conditioning systems shall be equipped with filters having efficiencies no less than those specified in table No. 2. Where two filter beds are required, filter bed No. 1 shall be located upstream of the air conditioning equipment and filter bed No. 2 shall be located downstream.

### TABLE 2. – FILTER EFFICIENCIES FOR CENTRAL VENTILATION AND AIR CONDITIONING SYSTEMS IN OUT-PATIENT SURGERY FACILITIES

<table>
<thead>
<tr>
<th>Area Designation</th>
<th>Minimum Number of Filter Beds</th>
<th>Filter Efficiencies Filter Bed No. 1</th>
<th>(Percent) Filter Bed No. 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitive Areas</td>
<td>2</td>
<td>25</td>
<td>90</td>
</tr>
</tbody>
</table>

(Includes operating rooms and recovery rooms)
Where only one filter bed is required, it shall be located upstream of the air conditioning equipment unless an additional prefilter is employed. In this case, the prefilter shall be upstream of the equipment and the main filter may be located further downstream.

(f) A manometer shall be installed across each filter bed serving sensitive areas or central air systems.

(g) Air handling duct systems shall meet the requirements of NFPA Standard 90A.

J. Electrical Requirements.

(1) Lighting.

(a) All spaces occupied by people, machinery, and equipment within buildings, approaches to buildings, and parking lots shall have lighting.

(b) A portable or fixed examination light shall be provided in each examination and treatment room.

(c) Operating rooms shall have general lighting in addition to local lighting provided by special lighting units at the surgical tables. Each special lighting unit at the tables, except for portable units, shall be connected to an independent circuit. Supplemental self contained emergency battery light units, with battery, trickle charger, supervisory and monitoring systems and controls shall be provided in each operating room.

(2) Receptacles (Convenience Outlets).

(a) Anesthetizing locations. Each operating room shall have at least three receptacles of the types described in NFPA Standard 56A. In locations where mobile X-ray is used, an additional receptacle, distinctively marked for X-ray use, shall be provided.

(b) Rooms. Duplex grounding type receptacles shall be installed in all areas in sufficient quantities for the tasks to be performed. A minimum of one duplex receptacle for each wall shall be installed in each work area or room other than storage or lockers. Each examination and work table shall have access to a minimum of two duplex receptacles.

(c) All electrical receptacles in examination, treatment, procedure, recovery and utility rooms, shall be a hospital grade type.

(3) Equipment Installation in Special Areas.

(a) X-ray Installations. Fixed and mobile X-ray equipment installations shall conform to article 660 of NFPA Standard 70.

(4) Emergency Electric Service.

(a) General. To provide electricity during an interruption of the normal electric supply, an emergency source of electricity shall be provided and connected to certain circuits for lighting and power in accordance with NFPA 76A.

(b) Sources. The source of this emergency electric service shall be: Emergency generating set. The required emergency generating set, including the prime mover and generator, shall be located on the premises and shall be reserved exclusively for supplying the emergency electrical system.

(c) Emergency electrical connections. Emergency electric service shall be provided to the distribution systems as follows: Circuits for the safety of patients and personnel.

(A) Illumination of means of egress as required in NFPA Standard 101.
(B) Illumination for exit signs and exit directional signs as required in NFPA Standard 101.

(C) Alarm systems including fire alarms and alarms required for nonflammable medical gas systems if installed.

(D) Paging or speaker systems if intended for communication during emergency.

(d) Circuits essential to care, treatment, and protection of patients.

(A) Task illumination and selected receptacles; drug distribution stations; operating and recovery rooms; treatment rooms; and nurses' stations.

(B) Nurses' calling system.

(C) Blood bank refrigeration, if provided.

(D) Equipment necessary for maintaining telephone service.

(e) Circuits which serve necessary equipment.

(A) Ventilation of operating rooms.

(B) Central suction systems serving medical and surgical functions.

(C) Equipment which must be kept in operation to prevent damage to the building or its contents.

(5) Details. The emergency electrical system shall be so controlled that after interruption of the normal electric power supply the generator is brought to full voltage and frequency. It must be connected within ten seconds through one or more primary automatic transfer switches to emergency lighting systems; alarm systems; blood bank; nurses' calling systems; equipment necessary for maintaining telephone service; and task illumination and receptacles in operating, emergency, recovery, and other critical patient areas. All other lighting and equipment required to be connected to the emergency system shall either be connected through the above described primary automatic transfer switches or through other automatic or manual transfer switches. Receptacles connected to the emergency system shall be distinctively marked. Storage-battery-powered lights, provided to augment the emergency lighting or for continuity of lighting during the interim of transfer switching immediately following all interruption of the normal service supply, shall not be used as a substitute for the requirement of a generator. Where stored fuel is required for emergency generator operation, the storage capacity shall be sufficient for not less than twelve hour continuous operation.

(6) Generator set locations shall be protected from the elements and against tampering.

K. Fire Alarm Systems. A manually operated electrically supervised fire alarm system shall be installed in each facility.

(c) Ownership and Administration.

(1) There shall be an organized governing authority with full legal authority and responsibility for the conduct of the surgical facility in a manner consonant with the objective of making available high quality patient care.

(2) Full and complete information shall be made available to the survey agency regarding the identity of each individual, group or corporation which has an ownership interest of ten percent or more in the facility.

(3) The governing authority shall have by-laws which shall identify the purposes of the facility, and the means of attaining them, which by-laws shall be dated, signed, and indicate periodic review and revision. These shall be available to all members of the governing body and all individuals to whom authority is delegated.

(4) These governing authority by-laws shall as a minimum contain:

(A) A delineation of the powers and duties of the officers, committees of the governing body and the chief executive officer.

(B) The qualifications for membership, the method of selection and the terms of office of members and chairmen of committees.

(C) A description of the authority delegated to the chief of medical staff or clinical director and the medical staff as a whole.

(D) A mechanism for approval of the appointments and annual reappointments of the members of the medical-surgical staff recommended by the medical-surgical staff to the governing body.

(E) A mechanism for the delineation and control of medical-surgical privileges and anesthesia privileges of members of the medical-surgical staff recommended by the medical-surgical staff to the governing body. This shall be based upon background, experience and demonstrated competence, adherence to the ethics of the profession and appropriate physical and mental health.

(5) The governing body shall approve the medical staff by-laws, its organizational structure and all rules and regulations.

(6) The governing body shall demonstrate an interest and understanding of the activities of the surgicenter: Fiscal; building and maintenance; and clinical.

(7) (A) The governing body shall have regular meetings, not less than four times a year and so often as its responsibilities require.

(B) The minutes of the governing body meetings will be recorded, dated, approved and signed.

(d) Chief Executive Officer.

(1) The governing body shall appoint a chief executive officer or administrator of the surgicenter who shall be qualified by education and experience appropriate to the discharge of his responsibilities.

(2) He shall be accountable to the governing body for his actions.

(3) His duties shall include the overall management of the operations of the facility, including the liaison and coordination of activities between the governing body and the medical and nursing staff.

(4) He shall be a member of the governing body and shall attend all meetings of the governing body and medical staff.

(e) Professional Staff.

(1) Clinical Director.

(A) The governing body shall appoint a clinical director, or chief of staff, accountable to it for his actions.

(B) He shall be qualified by training, demonstrated competence and judgment to manage the medical functions of the staff.

(C) He shall be delegated the authority to control the quality of medical-surgical care provided and to assure the effective discharge of the quality control review function of medical care.

(D) The members of the professional staff of the facility shall meet the requirements of Section 20-9 of the Connecticut General Statutes regarding who may practice medicine and Surgery.

(E) Shall be qualified by training and experience to perform the duties assigned.

(F) Shall also have privileges in a hospital licensed in Connecticut to perform the duty or procedure which will be done at the surgicenter.

(2) All appointments, reappointments and privileges will be granted by the governing body with recommendations from the medical staff.

(3) All appointments, reappointments and specific privileges granted to the medical-surgical staff will be recorded in the minutes of meetings of the governing body or of the medical staff and filed in the doctor's medical profile with an agreement.
signed by the physician to abide by the hospital by-laws, medical staff by-laws and rules and regulations.

(4) The medical staff shall develop medical staff by-laws, rules and regulations to govern its organization and conduct, which shall include, but not be limited to the following:
   (A) The officers of the medical staff, their duties, the qualifications for office, the term of office, the method of selection;
   (B) The basis on which recommendations will be made to the governing body regarding the appointments, reappointments and the privileges of staff members;
   (C) The committee structure of the medical staff;
   (D) The mechanism by which medical care will be assessed including the development and implementation of a medical care evaluation program. In accordance with the current requirements of the Joint Commission on Accreditation of Hospitals and the Professional Standards Review Organization in which:
      (a) Standards, norms, and criteria for care are developed for problems or disease categories.
      (b) The actual care provided is measured against these standards, norms and criteria in a study of patterns of care for these specific problems or disease entities.
      (c) A judgment or evaluation is made in the medical evaluation or audit procedure.
      (d) Appropriate action, as indicated, is taken and documented for observed variations and deficiencies in care as determined by the audit process.
      (e) The review to determine the appropriate utilization of facilities and equipment.
      (f) The development of a program to control facility-associated infections.
      (g) The development of a program to control the distribution and use of drugs and therapeutics; in accordance with the requirements of the State Department of Consumer Protection, Drug Control Division, and all applicable state and federal drug laws and regulations.
      (h) Requirements assuring that medical records shall be prepared and adequately maintained on each patient so as to explain and justify treatment and outcome.

(5) There shall be regular meetings of the medical-surgical staff with required attendance, except with appropriate justification of all physicians given privileges in the unit. The minutes of these meetings shall be recorded and shall reflect concern with the clinical care provided.

(6) At all times that there are patients in the unit there shall be a licensed physician on the premises.

(7) (A) The professional medical, surgical and nursing staff shall develop policies and procedures to assure high standards of professional practice on the unit. These shall be adopted, approved, placed in a manual made readily available for use by all professional staff and reviewed at least once a year, and as indicated, and revised as indicated.
   (B) Specific policies and/or procedures shall include, but not be limited to the following areas:
      (a) Requirement for, and necessary elements of, the pre-operative evaluation of the physical condition of all patients by a physician within a specific period before admission;
      (b) The necessary pre and postoperative tests;

(c) The categories of acceptable admission diagnoses and unacceptable admission diagnoses;
(d) Operating hours, method of selection of patients relative to age, sex, physical status;
(e) Requirements for written pre-operative and post-operative instructions to be explained to patients;
(f) Requirements for valid operative permits and signed informed consent forms;
(g) Operative procedures to be permitted and operative procedures to be excluded;
(h) Types of anesthesia that may be employed for specific procedures;
(i) Policies regarding use of laboratory tests, detection tests, treatment modalities and protective measures
(j) Guidelines covering emergency care;
(k) Requirements that patients' status shall be deemed appropriate prior to discharge as regards vital signs, voiding, temperature and other significant elements;
(l) Requirement that each patient is to have a responsible person available to accompany him or her on discharge unless otherwise authorized by a physician;
(m) Required policies relating to quality control, which include review and evaluation of surgical, anesthesiology and nursing practice as well as case review and review of patterns of care;
(n) A requirement that all tissue removed at surgery shall be submitted to a qualified licensed pathologist. Examinations will be performed on these tissues according to an established procedure approved by the pathologist and the medical director. The disposition of the tissue or the pathological report shall be appended to the patient record;
(o) Establishment of written agreements with hospital(s) in the immediate vicinity in the event it becomes necessary to transfer a patient(s);
(p) Policies regarding prevention and control of infections among patients and staffs;
(q) Appropriate referral and follow-up on patients and cooperative arrangements with referring physicians.

(8) Laboratory and Radiology.
   (A) Laboratory work performed shall be under the supervision of a qualified licensed pathologist, or shall be done by a licensed laboratory.
   (B) A qualified licensed radiologist shall supervise all radiological procedures.

(9) Anesthesia Services. The anesthesia services of the unit shall be under the supervision of a qualified anesthesiologist who shall be delegated the authority to:
   (A) Oversee the quality of anesthesia care provided by anesthesia personnel employed by the unit;
   (B) Assure the availability and proper functioning of such equipment as is necessary to administer anesthesia, and to provide necessary resuscitative measures including emergency cardiopulmonary resuscitation;
   (C) Develop regulations to assure anesthetic safety and recovery room patient support;
   (D) Administer a retrospective review of all anesthesia care. The anesthesiologist in charge shall have a major role in the development of

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policies and procedures to assure the satisfactory preanesthetic status of patients, including the decision regarding choice of anesthesia, preoperative medication, postoperative recovery room supervision, and suitable discharge status.

(f) Records and Reports.
(1) There shall be adequate provision for the retention and storage of all clinical records which shall ensure the safety of such records and the confidentiality of the information contained therein.

(2) Adequate space and equipment shall be provided for record keeping.

(3) A clinical record shall be started for each patient at the time of admission to the unit to include all appropriate and proper identifying data. Each patient's record shall contain sufficient information to justify the diagnosis and warrant the treatment given or services provided. Each entry in the record shall be signed by the person responsible for it immediately after service is rendered.

(4) All records shall be maintained in a safe manner for a minimum of five years following the discharge of the patient.

(5) The unit shall collect, retrieve and summarize data relating to program evaluation and in planning to meet needs of patients. This data should include at least the following: Total number of visits; number of patients seen; diagnosis; types and numbers of operative procedures performed; age distribution of patients; death and other untoward accidents or incidents. This report to be prepared on an annual basis and be available for review by the state department of health.

(6) There shall be an anesthesia record for each patient who receives anesthesia on the unit. This shall become a part of the medical record and shall include patient identification data, dosage and duration of anesthesia, a record of administration of other drugs or therapeutics.

(g) Nursing Staff.
(1) There shall be appointed as supervisor of the unit a registered nurse with a current license to practice in Connecticut. She/he should have special education and experience in operating and recovery room care. Qualifications of the supervisor and other personnel shall be verified in the form of listing current license numbers and in written job descriptions.

(2) If the unit is opened for a period of time beyond the normal work week of the R.N. supervisor and/or in her absence, an additionally qualified person shall be responsible for nursing services in the unit at these times.

(3) In addition to the supervisor there shall be additional licensed nurses with special training in surgery and recovery room care available. These additional personnel may serve as assistant or backup personnel under the direct supervision of a qualified registered nurse. A minimum of one registered nurse, in addition to the supervisor must be available at all times when there are patients in the unit. The minimum staffing ratio shall be such as to assure the provision of sufficient and adequate nursing care for the comfort, safety and welfare of all patients.

(h) Additional Personnel.
(1) All housekeeping and cleaning staff shall have and receive special training to ensure that technical procedures used in cleaning and housecleaning are developed and implemented to protect patients' health and safety.

(2) There shall be either available on staff or arrangements made for, the assistance of social workers, dietitians, psychologists and other professional staff as deemed necessary for the care of the patient.

(i) General.
(1) There shall be job descriptions indicating qualifications, training and/or past experience and responsibilities relating to the care of patients and/or equipment used in units for all personnel.

(2) There shall be a program of continuing staff education provided on a regularly scheduled basis in order to maintain and improve skills.

(3) There shall be appropriate sterilizing equipment of steam pressure type available. The size of the equipment shall be dependent upon the amount of pre-sterilized disposable equipment used in the unit.

(4) There shall be emergency equipment and drugs for resuscitation and defibrillation.

(5) The management, operation, personnel, equipment, facilities, sanitation and maintenance of the unit shall be such as reasonably to ensure the health and safety of public patients and staff at all times.

(6) Written fire and disaster plans shall be formulated and posted in a conspicuous location.

(j) Disaster Plan. The surgical unit shall develop a plan to cope with internal disasters including fire and loss of power. This plan shall include:

(1) The assignment of personnel to specific duties;
(2) Instruction in use of fire alarms, fire equipment and systems for notification of key personnel;
(3) Instructions in methods of fire containment;
(4) Procedures for evacuation of patients. Fire disaster drills shall be held at regular intervals, not less than quarterly including evacuation procedures to assure the effectiveness of these plans.

(k) Inspection and Licensure. The ambulatory surgical facility shall be inspected annually by the state department of health to test for ongoing compliance with these regulations. (Effective April 22, 1977.)