

## Section V

# Guidelines for Patient Care, Record Keeping & Medical Facilities

In order to treat patients in a safe, clean and sanitary environment the ICMS has developed the following facility guidelines.

Any clinic providing treatment to patients must display a professional appearance that is in keeping with a medical facility designed to carry out surgical procedures. The facility should be neat, comfortable and clean and should include a waiting area, business office and sanitary lavatory facilities. One or more dedicated exam rooms should be available that provide for privacy and treatment in a sanitary, orderly environment.

In keeping with this, the following must be maintained:

- The operating suite must be physically separate from the general office.
- The operating suite includes operating room(s), prep/scrub area, clean area, and/or dirty area, and recovery room.
- There is a room dedicated for use as an operating room.
- All major surgery is done in the separate and distinct operating room(s).
- The operating room(s) is adequately ventilated and temperature controlled.
- There is adequate operating room storage space to hold equipment, sterile supplies and medications. Storage space is adequate to minimize the need to leave the operating room for frequently used supplies, equipment and/or medication.
- There is sufficient storage space that provides easy access for identification and inventory of supplies.
- The operating room is properly cleaned, maintained and free of litter and clutter.
- Each operating room is of a size adequate to allow for the presence of all equipment and personnel necessary for the performance of the surgical procedures, and must comply with applicable local, state or federal requirements. Additionally, all facilities must have a minimum of four (4) feet (48 inches) of clear space on each side of the operating table to accommodate emergency personnel and equipment in case of emergency, and permit the safe transfer of the patient to a gurney for transport
- OR:
- Facility personnel can physically demonstrate to the inspector that the emergency criteria, as stated above, can be met in the operating room space available.

- Unauthorized individuals are deterred from entering the operating room suite either by locks, alarms, or facility personnel.
- Sterile supplies are stored away from potential contamination in closed cabinets/drawers or if not, away from heavy traffic areas.
- Sterile supplies are labeled to indicate sterility, and are packaged and sealed to prevent accidental opening.
- Each sterilized pack is marked with the date of sterilization and, when applicable, with the expiration date.
- When more than one autoclave is available, each pack must additionally be labeled to identify in which autoclave it was sterilized.
- If one sink is used both for dirty instruments and to scrub for surgery, there is a written policy to clean and disinfect the sink prior to scrubbing hands.
- If a pre-existing sink is present in the operating room, a written policy to prohibit the use of the sink during sterile surgical procedures must be in place.
- The facility has at least one chemical (Chemclave) or gas (ethylene oxide) autoclave.
- Gas sterilizers are vented.
- Where applicable, all instruments used in patient care are sterilized.
- A high-level disinfection is used only for non-autoclavable endoscopic equipment, and in areas that are categorized as semi-critical where contact will be made with mucus membrane or other body surfaces that are not sterile.
- A weekly spore test, or its equivalent, must be performed on each autoclave and the results filed and kept for a minimum of three (3) years.
- If a spore test is positive, there must be a written protocol for remedial action to correct the sterilization process.
- Instrument handling and sterilizing areas must be cleaned and maintained on regularly scheduled basis.
- There must be a strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.
- The instrument preparation and assembly area (clean utility area) should be separated by walls or space from the instrument cleaning area (dirty utility area) or if not, there is a policy to clean and disinfect the dirty utility area before preparing and assembling packs for sterilization.
- Between operative cases, the operating room(s) must be cleaned with disinfectants according to an established schedule adequate to prevent cross-contamination.
- Scrub suits, caps or hair covers, gloves, operative gowns, masks and eye protection must be utilized for all appropriate surgery.
- A sterile field is routinely used during all operations.
- Surgical scrub soap and/or alcohol cleansers must be provided for the surgery room staff.

- All blood and body fluid spills are cleaned using germicides that are virucidal, bactericidal, tuberculocidal and fungicidal.
- A written protocol has been developed for use by housekeeping personnel for cleaning of floors, tables, walls, ceilings, counters, furniture and fixtures of the surgical suite.
- All openings to outdoor air must be effectively protected against the entrance of insects, animals, etc.
- The operating room ceiling surface or drop-in tiles are smooth, washable and free of particulate matter that can contaminate the operating room.
- The walls and counter tops are covered with smooth and easy to clean material that is free from tears, breaks or cracks.
- The floors are covered with an easily cleaned material which is smooth and free from breaks or cracks. If the floors contain seams or individual tiles, they are sealed with an impermeable sealant other than silicone.
- All equipment is on a preventative maintenance schedule with records kept for a minimum of at least three (3) years. Stickers may be placed on individual equipment; however written records must be maintained.
- All equipment repairs and changes are done by a bio-medical technician with records kept for a minimum of three (3) years.
- The operating room must have the following:
  - An adequate operating room table or chair,
  - Adequate lighting in the ceiling,
  - An EKG monitor with pulse read-out is present,
  - Blood pressure monitoring equipment is present,
  - A standard defibrillator, or an Automated External Defibrillator unit (AED),
    - Equipment is checked at least weekly for operability, and the test results are kept for a minimum of three (3) years.
  - Sequential compressive devices (SCD) are employed for surgical procedures of one hour or longer, except for procedures carried out under local anesthesia,
  - Positive pressure ventilation device (e.g. Ambu® bag),
  - Source of O<sub>2</sub>,
  - Source of suction,
  - A machine with a purge system to extract exhaled gaseous air to out-of-doors, or to a neutralizing system,
  - An inspired gas oxygen monitor on the anesthesia machine (if anesthesia is used),
  - A CO<sub>2</sub> monitor is present and is used on all general anesthesia cases (if anesthesia is used), and
  - An emergency power source, (e.g., a generator or battery powered inverter), with capacity to operate adequate monitoring, anesthesia (if anesthesia is used), surgical equipment, cautery and lighting for a minimum of two (2) hours.

- The emergency power equipment is routinely checked to insure proper function, and the test results are filed and kept for a period of three (3) years.
- All medical hazardous wastes are stored in acceptable bio-hazard containers, and separated from general refuse for special collection and handling.
- Used disposable sharp items are placed in puncture-resistant containers located close to the area in which they are used.
- There must be a written policy for cleaning of spills which may contain blood borne pathogens.

### **Guidelines for Pre-Operative Care Procedures**

A policy for a pre-operative review is in place and practiced and documented prior to every procedure.

Physician and the operating room team reviews all medical records, imaging studies, any implants identified.

Any procedures calling for right/left distinction; multiple structures (breasts, eyes, fingers, toes, etc.) is marked prior to the procedure while the patient is awake and aware.

Pre-Operative Verification is completed by at least two (2) members of the surgical team.

### **Guidelines Post Operative Care Procedures (Anesthesia)**

Patients transferred to the Post Anesthesia Care Unit (PACU) are accompanied by a member of the anesthesia team who is knowledgeable about the patient.

Patients transferred to the PACU will be continually evaluated and monitored as needed during transport.

There is a written policy that assures that the following actions are taken and noted:

- Documentation of patient's time of arrival,
- Assessment of the patient by the anesthesia recovery staff, as well as by a responsible physician,
- Transmission of a verbal report on the patient to the PACU team from a member of the anesthesia team who accompanies the patient, and
- Transfer of information concerning the preoperative condition of the patient and the surgery – anesthesia course.

A written, accurate post-anesthetic care report is maintained.

All recovering patients are observed and supervised by trained medical personnel in the recovery area.

There is a written policy that whenever parenteral sedation, dissociative drugs, epidural, spinal or general anesthesia is administered, a physician is immediately available until the patient is discharged from the PACU.

A physician determines that the patient meets discharge criteria based upon input from the PACU nurse, and that physician's name must be noted on the record.

Sufficient space to accommodate the necessary personnel, equipment and monitoring devices is available.

There is an adequate and reliable source of suction.

There are sufficient electrical outlets are available, labeled and grounded to suit the location (e.g. wet locations, cystoscopy-arthroscopy) and connected to emergency power supplies where appropriate.

There is adequate illumination for patients, machines and monitoring equipment, which can include battery powered illuminating systems.

Emergency cart is available with defibrillator, necessary drugs and other CPR equipment.

There is a separate and adequately sized recovery room within the operating room suite.

The room is equipped and readily accessible to handle emergencies.

There is a recovery room record that includes vital signs, medications and nurse's notes.

There are written post-operative instructions, including procedures for emergency situations that are given to an adult who is responsible for the patient's care and transportation.

Patients are required to meet criteria for physiological stability before discharge, including vital signs and sensorium.

Unless they are having local anesthesia only, patients are transported from the facility by wheelchair or gurney to a waiting vehicle or to another facility with a responsible adult.



Warnings and signage exists to warn those whose health may be affected by x-ray.

There is a written protocol for the return to the operating room for patient emergencies.

### **Guidelines Post Operative Care Procedures (Non-Anesthesia)**

Patients transferred to the PACU will be continually evaluated and monitored as needed during transport.

There is a written policy that assures that the following actions are taken and noted:

- Documentation of patient's time of arrival,
- Assessment of the patient by the recovery staff, as well as by a responsible physician,
- Transmission of a verbal report on the patient to the PACU team from a member of the recovery team who accompanies the patient, and
- Transfer of information concerning the preoperative condition of the patient and the surgery course.

A written, accurate anesthetic operative care report must be maintained.

All recovering patients are observed and supervised by trained medical personnel in the recovery area.

A physician must determine that the patient meets discharge criteria based upon input from the PACU nurse, and that physician's name must be noted on the record.

Sufficient space to accommodate the necessary personnel, equipment and monitoring devices is available.

There is an adequate and reliable source of suction.

There are sufficient electrical outlets are available, labeled and grounded to suit the location (e.g. wet locations, cystoscopy-arthroscopy) and connected to emergency power supplies where appropriate.

There is adequate illumination for patients, machines and monitoring equipment, which can include battery powered illuminating systems.

Emergency cart is available with defibrillator, necessary drugs and other CPR equipment.

There is a separate and adequately sized recovery room within the operating room suite.

The room is equipped and readily accessible to handle emergencies.

There is a recovery room record that includes vital signs, medications and nurse's notes.

There are written post-operative instructions, including procedures for emergency situations that are given to an adult who is responsible for the patient's care and transportation.

Patients are required to meet criteria for physiological stability before discharge, including vital signs and sensorium.

Unless they are having local anesthesia only, patients are transported from the facility by wheelchair or gurney to a waiting vehicle or to another facility with a responsible adult.

Warnings and signage exists to warn those whose health may be affected by x-ray.

There is a written protocol for the return to the operating room for patient emergencies.

### **Guidelines for Operating Theatre Procedures**

There is a written protocol for:

- A situation in which the surgeon becomes incapacitated,
- A situation in which the anesthesiologist or CRNA becomes incapacitated,
- Response to power failure emergencies,
- Transferring patients in an emergency, and
- The emergency evacuation of the facility.

There is a written transfer agreement with a local accredited or licensed acute care hospital within 30 minutes driving time and is approved by the facility's medical staff, or the operating surgeon has privileges to admit patients to such a hospital.

Additionally, every facility must:

- Be equipped with heat sensors and/or smoke detectors,
- Have an adequate number of fire extinguishers, and
- Have sufficient emergency lights for exit routes and patient care areas in case of power failure.

There must be a written protocol that:

- If blood is used, that it is typed, cross-matched, checked and verified,
- Outdated medications are removed, and
- Medical records are legible, documented and completed accurately.

### **Guidelines for Patient Medical, Treatment History and Examination Records**

A complete record of the patient's medical history and physical examination by the physician must be kept. Patient records must be complete, compiled and stored together and available for review by the inspector.

Medical records have been retained and available for audit for 20 years.

Medical records are filed for easy accessibility, and must be maintained in the facility regardless of the location of the operating physician's office.

Medical records must be kept secure and confidential consistent with local patient privacy regulations.

The medical record must contain:

- Signed copy of an informed consent,
- A copy of the patient candidacy grading form,
- A completed pre-operative checklist,
- The completed and signed ICMS Treatment Registry Patient Form,
- The complete and current medical history, taken on the same day as the treatment, and recorded by the physician,
- The history and physical examination should cover the organs and systems commensurate with the treatment procedure(s),
- The completed pre-operative assessment of the patient completed by the physician,
- The pre and post anesthesia evaluation (if anesthesia is used),
- The completed medication reconciliation / verification form,
- The printed or written copies of all Laboratory, Pathology, X-Ray, Consultation, and Treating Physician Reports.

The pre-operative medical record must include the following information:

- Drug allergies/sensitivities,
- Current medications,
- Previous serious illness,
- Current and chronic illness,
- Previous surgery, and



- Bleeding tendencies.

### **Guidelines for Physician Treatment Log Maintenance**

Physicians are required to keep, and produce for the inspector, if needed, a separate treatment log of major cases (excluding procedures done solely under local anesthesia) either in a hard copy bound log with sequentially numbered pages, or in a secured computer log.

The physician treatment log contains sequential numerical listing of patients either consecutive numbering from the first case carried out in the facility or consecutive numbers starting each year.

The physician treatment log must contain:

- Date of treatment,
- The patient's name and/or identification number,
- The physician's name,
- The type of anesthesia administered (if any),
- The name of person(s) administering anesthesia (if any),
- The name of person(s) assisting surgeon (M.D., registered nurse, scrub tech/circulating registered nurse, Physician's assistant),
- The vital signs recorded during surgery,
- A list of all medications given to a patient are recorded including date, time, amount and route of administration,
- A list of all intravenous and subcutaneous fluids given pre-operatively, intra-operatively and post-operatively are recorded, and
- Records that the post-operative vital signs have been recorded until the patient is discharged from the facility.

### **General Guidelines for Clinic Operation**

The Medical Director of the facility must meet the following qualifications:

- A valid medical degree,
- Is a physician currently licensed by the state / province in which the facility is located,
- Is a physician certified or eligible for certification by a recognized medical board, and
- Is actively involved in the direction and management of the facility.

All operating suite personnel are under the immediate supervision of a registered nurse, a physician other than the operating physician, or physician's assistant.

All staff must meet acceptable standards as defined by their professional governing bodies, where applicable.

There is a regularly employed and licensed registered nurse, physician other than the operating surgeon, or physician's assistant designated as the person responsible for patient care in all areas of the facility, in accordance with state law.

The operating room personnel have knowledge to treat cardiopulmonary and anaphylactic emergencies. At least one member of the operating room team, preferably the surgeon or the anesthesia care giver, holds current ACLS certification.

The operating room personnel are familiar with equipment and procedures utilized in the treatment of the above emergencies.

Personnel are properly trained in the control procedures and work practices that have been demonstrated to reduce occupational exposures to anesthetic gases.

### **Guidelines for Patient Record Maintenance**

A proper and complete record of the patient's treatment must be kept. This record must include the following a written record of:

- A physical evaluation of the patient by the physician prior to the treatment,
- The general health status of the patient prior to the treatment,
- A patient evaluation for objective indications of disease severity,
- A patient evaluation for co-morbid conditions,
- A patient evaluation for possible contraindications,
- A patient evaluation for factors that may reduce outcome,
- An evaluation of the patient for any evidence of acute or chronic infection,
- A prospective candidacy of the patient grading the patient as a good, fair or poor candidate for the treatment, and
- A signed informed consent that includes a discussion with the patient of the risks and benefits of the procedure as well as alternatives to the procedure.

### **Guidelines for the Use of Anesthesia**

All anesthetic, other than topical or local anesthetic agents, must be delivered by:

- An anesthesiologist,
- A CRNA under physician supervision (if required by state, local or federal law or by a policy adopted by the facility), or
- An anesthesiology assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants under direct supervision of an anesthesiologist.

Parenteral sedation, other than propofol, may be administered by a registered nurse under the supervision of a qualified physician.

Prior to use of anesthesia, a physician must:

- Examine and determine the medical status of the patient.
- Verify that the anesthesia care plan, based on a review of the medical record, medical tests, consultations and prior anesthetic experiences has been developed and documented.
- Verify that the anesthesia care plan is based on medical examination and assessment of any conditions that might affect the preoperative risk.
- Verify that the patient or a responsible adult has been informed about the anesthesia care.

A physician must be present when any anesthesia, other than local anesthesia, is administered.

While under anesthesia, circulation is monitored by one or several of the following:

- Continuous EKG during surgery.
- Blood pressure.
- Heart rate every 5 minutes (minimum).
- Pulse oximetry.
- Heart auscultation.
- Intra-arterial pressure.
- Ultrasound peripheral pulse monitor, pulse plethysmography or oximetry.
- “Forced air warmers,” blanket warmers, or other devices must be used to maintain patient temperature.