Non-Hospital Medical/Surgical Facilities

Standards

December 2011

The College of Physicians & Surgeons of Manitoba would like to acknowledge The College of Physicians & Surgeons of Alberta for permitting reproduction in part of the document "Non-Hospital Surgical Facility, Standards and Guidelines", March 2009.

Preface

The profession, through and with The College of Physicians & Surgeons of Manitoba (CPSM), has the duty to serve and protect the public interest by regulating the practice of medicine and governing in accordance with *The Medical Act.*

Accreditation of Non-Hospital Medical/Surgical Facilities (NHMSF) is governed by By-Law 3D through the Standards Committee. The Committee advises Council of the CPSM in matters pertaining to NHMSFs that do not fall under the jurisdiction of Regional Health Authorities.

Each non-hospital medical/surgical facility, its professional and technical personnel, its equipment, its space and its safety procedures must at all times meet the minimum standards established by the Committee.

In this document, the term "must" refers to a mandatory requirement. The term "may" means the physician may exercise reasonable discretion.

Definitions

Accreditation – The approval granted by the CPSM to a non-hospital medical/surgical facility to carry out certain diagnostic and/or treatment procedures.

Accreditation Process – A review process conducted by the CPSM to determine if NHMSFs meet or exceed standards as set by the CPSM.

Adverse Event – An unintended injury or complication that is caused by healthcare management rather than the patient's underlying disease and that leads to death or disability or that requires additional use of hospital or health care organizational resources such as prolonged hospital stay, additional testing or interventions. (Canadian Adverse Event and Learning System - Consultation Paper CPSI July 2008)

Alcohol – 70% isopropyl or ethyl alcohol.

Automated Endoscope Reprocessor (AER) – Machines designed to assist with cleaning and disinfecting of endoscopes.

Certificate of Accreditation – A certificate issued to a non-hospital medical/surgical facility by the committee of the college certifying that it has received accreditation.

Clean – Visibly free from debris. Cleaning involves physical removal of blood, mucous, vomitus, fecal matter and other organic residue.

Committee – The Standards Committee of the CPSM.

Conditional Accreditation – Accreditation granted to a facility that does not comply with the relevant standards but where the Committee is of the opinion that it is in the public interest to permit the facility to operate while it corrects specified deficiencies.

Conscious Sedation (Procedural Sedation/Analgesia) – An altered or depressed state of awareness or perception of pain brought about by pharmacologic agents and which is accompanied by varying degrees of depression of respiration and protective reflexes in which verbal contact with the patient can be

maintained. No distinction is made between light and deep conscious sedation for credentialing or monitoring purposes. The provision of conscious sedation includes, but is not limited to, the use of any IV agent for this purpose. All of the above require the monitoring of vital signs. For the purposes of this document, the use of oral pre-medication alone or in combination with local anesthesia is not defined as conscious sedation.

Critical Medical Devices – Devices that contact sterile tissue or the vascular system and require sterilization (surgical instruments, biopsy forceps, suture scissors, devices entering sterile body cavities, etc.).

Enzymatic detergent – Low-sudsing enzymatic detergent formulations recommended for cleaning endoscopes. These are combinations of detergent and enzymes capable of digesting organic material such as blood and mucous without damage to the instrument.

Endoscopes–Flexible – Flexible fiberoptic or video endoscopes used in the examination of the hollow viscera (bronchoscope, colonoscope, duodenoscope, gastroscope, sigmoidoscope, etc.).

Endoscopes–Rigid – Small straight scopes generally without lumens (arthroscope, laparoscope, cystoscope, etc.).

General Anesthesia – A controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including inability to maintain an airway independently, or to respond purposefully to physical stimulation or verbal command; produced by pharmacologic or non-pharmacologic methods, alone or in combination.

High Level Disinfectants – High Level Disinfectant processes destroy bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non lipid) viruses but do not necessarily kill bacterial spores. High Level Disinfectant chemicals (also called chemical sterilants) must be capable of sterilization when contact time is extended. Items must be thoroughly cleaned prior to High Level Disinfection.

Hospital – Means a hospital under *The Hospitals Act,* and includes the Misericordia Health Centre.

Low Level Disinfectants – Low level disinfectants kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses (e.g., hepatitis B, C, Hantavirus, and HIV). Low Level Disinfectants do not kill mycobacteria or bacterial spores. Low Level Disinfectants are typically used to clean environmental surfaces.

Medical Director – The physician appointed as director of a NHMSF in accordance with CPSM by-laws.

Minimal Sedation (Anxiolysis) – Pharmacologically induced state during which patients respond to verbal stimulation. Cognitive function and coordination may be impaired but ventilatory and cardiovascular functions are unaffected. Local or regional blocks may be used concurrently with sedation to optimize analgesia.

Non-Critical Medical Devices – Medical devices that come into contact with only intact skin (not mucous membranes) (blood pressure cuffs, stethoscopes etc.).

Non-Hospital Medical/Surgical Facility – Any facility where one or more physicians perform:

(i) Any procedure that is carried out with the concurrent use of:
(a) conscious sedation, or

(b) regional or general anesthesia, to a degree that requires monitoring of vital signs.

(ii) Any procedure that the Committee directs in writing must be performed in an accredited non-hospital medical/surgical facility in order to meet the standard of care for that procedure.

Privileges – Means the authority to admit and treat patients at a facility.

Procedures – Refers to medical and surgical diagnostic and treatment procedures approved by the Committee for NHMSF and includes endoscopic, diagnostic, interventional and invasive procedures.

Provisional Accreditation – Granted for the operation of a facility, in circumstances which the committee deems appropriate, pending the completion of the accreditation process.

Semi-Critical Medical Devices – Devices that come into contact with mucous membranes or non-intact skin and require a minimum of high level disinfection (vaginal specula, nasal specula, vaginal/anal ultrasound probes, endoscopes, laryngoscopes etc.).

Sterilization – the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Items must be thoroughly cleaned before effective sterilization can take place.

Ultrasonic Cleaner – An instrument reprocessing unit that uses ultrasound waves to produce tiny air bubbles in a cleaning solution. The imploding of the air bubbles dislodges debris even in hard to reach areas of instruments.

Table of Contents

A. Introduction

The Committee oversees all issues related to medical, surgical and anesthetic services that may include, but are not limited to, establishing:

- evidence-based standards for NHMSF;
- minimum criteria for medical directors for NHMSF;
- minimum qualifications for a physician to obtain privileges at NHMSF;
- standards of patient care and safety which must be met in a NHMSF;
- an accreditation process for NHMSF.

Types of Surgical Procedures

Procedures suitable for NHMSF must entail:

- a minimal risk of post-operative hemorrhage or fluid imbalance
- a minimal risk of post-operative airway compromise
- post-operative pain manageable by outpatient pain techniques
- post-operative care managed by the patient and/or a responsible adult
- a rapid return to normal fluid and food intake

Each NHMSF must perform only those procedures as outlined in their respective Certificate of Accreditation as granted by the CPSM.

Role of the College

Non-Hospital Medical/Surgical Facilities must be accredited by the CPSM prior to offering any procedures to the public.

Requirements for accreditation include:

(1) Compliance with minimum standards as set by the Committee.

(2) Medical director acceptable to the Committee.

(3) A written agreement with a hospital or RHA whereby the hospital or RHA agrees to provide emergency treatment if a patient must be transferred from the NHMSF.

(4) Completion of a pre-visit questionnaire (See Appendix A).

(5) An on-site survey by a team of health care professionals, at least one of whom is a physician. The surveyors will have expertise in the appropriate area of practice and will be designated by the Committee to conduct the inspection.

(6) A written report must be generated within six weeks of the site survey, with the Committee findings. Where no deficiencies are identified, the Committee shall grant full accreditation specifying the procedures for which the NHMSF has received accreditation. Where deficiencies are identified the Committee may:

(a) Permit the NHMSF to operate while it corrects specified deficiencies by a fixed deadline. A follow-up survey must occur before full accreditation is granted.

(b) If, in the opinion of the Committee, the public is at risk, accreditation shall not be granted. When deficiencies have been corrected to comply with minimum standards, the Committee must re-survey the facility.

Once granted, accreditation shall be for a period of time no greater than 5 years or as determined by the Committee.

B. Personnel

1. Medical Director Responsibilities

(1) Each NHMSF must have a medical director who is a physician licensed to practice medicine in Manitoba.

(2) The Medical Director is personally responsible for the following:

(a) Effective control for the operation and administration of the NHMSF.
(b) Supervision of all professional, technical and administrative activities.
(c) Compliance with the by-laws and with the minimum standards established by the Committee.
(d) Ensuring up to date policy and procedural manuals are in place.
(e) Ensuring that only those procedures outlined in the Certificate of Accreditation are performed.
(f) That the roles and responsibilities of all personnel are documented and understood.
(g) Sufficient numbers of appropriately trained staff are present prior to, during and following procedures.
(h) That procedures and equipment are appropriate and safe and that the NHMSF has arrangements in place for emergency transfer and admission of patients to hospital.
(i) That a process is in place to monitor and report infections, complications and adverse events which impact on patient or staff safety.
(j) The review and screening of those applicants requesting privileges within the NHMSF. Once satisfied that the applicant is a suitable candidate, the name of the physician and the procedures to be performed must be forwarded to the Committee.
(k) Preparing the Facility Annual Report for the Committee (Appendix D).
(l) Monitoring that staff are current with ACLS or BLS.
(m) Application for accreditation prior to offering any procedures to the public.
(n) The completion of the application for accreditation on the Non-Hospital Medical/ Surgical Facility Accreditation Application Form. (Appendix I). Complete details will be required on the Pre-Visit Questionnaire (Appendix A).
(o) Application for renewal of accreditation at least 6 months prior to the date the certificate of accreditation is to expire. The re-accreditation process is the same process as for initial accreditation.
(p) To ensure the payment of all expenses, charges and fees including any licence fees imposed by the committee in the respect of the administration of the By-law governing the accreditation of NHMSF.

2. Physicians Practising in Non-Hospital Medical/Surgical Facilities

All physicians seeking privileges in NHMSF must be licensed to practice medicine in Manitoba.

(1) Application for Privileges:

(a) The physician must apply in writing indicating the specific procedural privileges being applied for to the Medical Director of the NHMSF.

(b) The physician must provide information concerning privileges currently held in all facilities in Manitoba, including details of the number of similar procedures performed within the last two years.

(c) The applicant must submit the names of two references who will be contacted by the Medical Director for the purpose of assessing qualifications.

(2) Qualifications:

(a) Physicians who administer general anesthesia or major regional blocks in a NHMSF must possess certification in anesthesia from The Royal College of Physicians & Surgeons of Canada or have completed anesthesia training in an approved teaching centre acceptable to the CPSM.

(b) Physicians who administer IV sedation in a NHMSF must be qualified to administer general anesthesia or have completed training in the administration and monitoring of IV sedation (such as required by the Winnipeg Regional Health Authority (WRHA).

(3) All physicians who perform procedures/surgery under anesthesia, major regional block or IV sedation must have been granted privileges to perform eligible procedures in the facility.

(4) ACLS certification is recommended for physicians practising in a NHMSF.

3. Nursing and Support Staff

(1) A nurse whose qualifications are acceptable to the Medical Director must be present and in charge of nursing and para nursing personnel. This nurse must also have knowledge of and be in charge of the non-anesthetic equipment, critical supplies, personnel assignments and their duties.

(2) The following delegated functions must only be provided by personnel who are licensed to perform the following procedures, i.e. MD, RN, and LPN:

(a) Preparation of medications
(b) Administration of medications
(c) Documentation of medications administered to patients
(d) Monitoring of vital signs during a procedure shall be a suitably trained nurse or physician.
(e) Recovering patients from general anesthesia, major regional blocks or IV sedation shall be a suitably trained nurse or physician.

(3) All individuals (including physicians) providing clinical care must maintain current certification in cardiopulmonary resuscitation as specified by the Heart and Stroke Foundation of Canada. ACLS (Advanced Cardiac Life Support) is recommended.

(4) Personnel records must be maintained in confidential files on all staff and must include:

(a) A completed application form
(b) A record of orientation to the facility and assigned duties
(c) Proof of current registration or certification
(d) Proof of current BLS /ACLS certification

(e) Record of immunization as specified by Manitoba Health in the Manitoba Immunization Schedules Reference Guide for Health Professionals

(f) Documentation of ongoing continuing education and/or training.

(5) All personnel must have full knowledge of surgical procedures and asepsis and be approved by the Medical Director. Operating room technicians practicing in NHMSF must be certified by the recognized standard.

(6) Immunization for employees should meet the standards of the Canadian Immunization Guide at www.phac-aspc.gc.ca.

C. Facility Standards

1. General

(1) Facilities must comply with all applicable provincial and/or municipal building codes and fire regulations.

(2) Facilities should be accessible to persons with disabilities.

(3) Facilities must be accessible to ambulances, emergency responders and their equipment should the patient require emergency care or transfer to a hospital.

(4) Facility layout must provide for adequate space conducive to safe and private patient care and patient flow.

(5) Facilities must provide for separate administration areas, patient waiting and care areas, clean utility, dirty utility and non-sterile storage areas and staff areas.

(6) Facilities must provide a designated patient washroom that is wheelchair accessible.

(7) The dirty utility (soiled) room must be physically separated from other work areas.

(8) Facilities must provide accommodation that permits the monitoring of vital signs and initiation of emergency resuscitation procedures at any time.

(9) Sterile and non-sterile areas must be clearly identified.

(10) Facility doors and corridors must be wide enough for stretcher access.

(11) Facilities must provide adequate waiting areas to accommodate patients~~,~~ and escorts.

(12) Wheelchairs and/or stretchers must be readily available.

(13) Emergency light source (battery-operated or emergency power source) must be available in all areas.

(14) Fire extinguishers must be available according to Manitoba Fire Codes.

(15) Adequate sterilization equipment must be available and in working order as per infection control standards.

(16) Floors in the operating rooms must be smooth and washable. If individual tiles are used, they must be sealed with a polyurethane sealant. Operating room walls must be smooth and easy to wash.

(17) Facilities must provide for appropriate hand washing equipment and proper towel usage and disposal.

(18) Facilities must provide a designated, secure and locked cabinet for controlled medications and maintain records of usage.

(19) Facilities must provide all equipment for the administration of intravenous fluids.

(20) Facilities must ensure that all openings to the outer air effectively protect against the entrance of insects or animals by self closing doors, closed windows, screening, controlled air current or other effective means.

2. Administration

(1) Ownership of the non-hospital medical/surgical facility must be clearly identified to the College. The Medical Director must comply with all criteria as per Section B Personnel.

(2) Updated Policy Manuals must be available to all personnel and contain:

(a) Written descriptions of the administrative responsibility for the operation of the facility.
(b) A current organizational chart.
(c) Current written job descriptions outlining the duties and responsibilities of all personnel in the facility.

3. Operating Room

(1) Facilities must maintain at least one operating room that is used exclusively for surgery, in order to protect the integrity of supplies, equipment and cleanliness.

(2) The operating room must be of sufficient size to accommodate required equipment and personnel.

(3) Ceilings in operating rooms requiring a sterile field must be constructed of a smooth washable surface.

(4) There should be physical segregation, with doors between the operating room and the rest of the facility.

(5) The operating table/chair must permit patient restraints and positioning.

(6) The operating room table/chair must be suitable for the procedures performed, including:

(a) Adequate range of movement for anesthetic procedures.
(b) Adjustable headrest to facilitate intubation.

(7) Suitable surgical lighting and emergency lighting sources must be available.

(8) The electrical system must comply with current codes and be accessible and adequate for all necessary equipment. (Extension cords must be appropriately rated and used in a safe manner when necessary.)

(9) There must be backup power for anesthetic machines and surgical equipment.

(10) Suction equipment and oxygen must be present in the operating and Post Anesthesia Care areas at all times with secondary back-up suction and oxygen available.

(11) All equipment for the administration of anesthesia must be readily available, clean and properly maintained by trained personnel.

(12) Facilities must keep an operative log book that includes the patient name, the date of the procedure, and the type of procedure performed. The name of the surgeon and the name of the anesthesia provider must be recorded.

(13) A stationary telephone must be available.

(14) Facilities must have a system in place to address medical and non-medical emergencies.

(15) Non-flammable Medical Gas Piping Systems must have been tested in accordance with the Manitoba Building Code.

(16) A letter from the Safety Code Officer verifying compliance with the Non-flammable Medical Gas Piping Systems must be available.

4. Post Anesthesia Care Unit (PACU)

(1) Facilities must provide a PACU which is separate from the operating room if surgical cases are carried out while other patients are recovering from anesthetics or IV sedation.

(2) The size of the PACU will depend on projected use:

(a) It must accommodate the volume of patients expected for minimum of 2 hours operating room time, i.e. 1 hour cases = 2 patients, .5 hour cases = 4 patients.
(b) It must allow easy access for transfer of a patient to or from a stretcher and performance of emergency procedures.

(3) Suction and oxygen must be readily available in the PACU with a secondary back-up available.

(4) There must be ready access to a sink for hand washing.

(5) Facilities must have electrical outlets available to supply power to monitoring equipment. (Extension cords must be appropriately rated and used in a safe manner when necessary.)

(6) An emergency lighting source must be available in case of a power failure.

(7) A stationary telephone must be available.

(8) Facilities must have a system in place to address medical and non-medical emergencies.

(9) The following equipment and supplies must be readily available:

(a) ECG monitoring
(b) Airway bag-valve mask
(c) IV supplies
(d) medical/surgical supplies
(e) medications and narcotics

D. Equipment and Supplies

1. Anesthetic and Resuscitation Equipment

(1) All equipment for the administration of anesthetics must be kept readily available, clean and properly maintained by trained personnel.

(2) A log describing scheduled maintenance and inspection of equipment must be kept current and readily available.

(3) A certified anesthetic machine must be present which only handles non explosive anesthetics. A CO_2 analyzer must be attached to the equipment utilized for general anesthesia. The general anesthesia equipment must have an inspired O_2 monitor with an alarm for low O_2 concentration.

(4) Dedicated suction must be available to the anesthesia provider.

(5) If a mechanical ventilator is utilized, it must have a continuous use device that will indicate a disconnection from the O_2 source by an audible signal. There must be low and high pressure alarms on the ventilator.

(6) Resuscitation equipment must be present. Endotracheal tubes, airways, laryngoscope and oxygen sources with positive pressure capabilities must be provided. Emergency drugs must be present (Appendix C). An eight hour supply of oxygen @ 5L/min must be present.

2. Medications

(1) Facilities must maintain a medication inventory.

(2) Facilities must perform scheduled inspections of inventory for the purpose of restocking and renewal of outdated supplies.

(3) All medication must be stored according to manufacturer recommendations.

(4) The use of multi-dose vials is strongly discouraged. If they are used, care must be taken to not contaminate the contents of the vial. The rubber diaphragm must be wiped with alcohol, and a new sterile needle and syringe must be used each time the vial is entered. The date the vial is first used must be recorded on the vial. The opened vial should be discarded within a period recommended by the manufacturer or within one month.

(5) All medication dispensed to patients at time of discharge must be recorded on the clinical record. Written and verbal instructions must be provided to the patient and/or escort.

(6) Controlled medications must be kept in a designated secure and locked cabinet.

(7) A log of controlled medications must be maintained with the name and quantity of the medication and date added to or removed from inventory.

(8) Upon administration of a controlled medication the following information must be recorded on the log:

(a) Patient name
(b) Drug name and dose removed from inventory
(c) Date
(d) Name of qualified individual dispensing the medication
(e) Reconciliation of actual and expected amount of medication remaining.

(9) Qualified individuals include an RN, LPN or a physician. The qualified individuals are responsible to ensure end of day reconciliation of actual and expected inventory of controlled medications verified by the signatures of the two qualified individuals.

(10) Any discrepancies of controlled substances must be investigated and documented.

3. Laser Equipment

(1) All NHMSF using Laser Equipment must develop and implement safe work procedures respecting the use of lasers.

(2) The safe work procedures on lasers must meet the requirements of CSA Standard Z386-01 (R2006) Laser Safety in Health Care Facilities.

(3) CSA Standards must be available.

4. Blood Products

(1) Any blood and/or blood products administered in a NHMSF must be in accordance with Canadian Blood Services standards and procedures.

(2) The Canadian Blood Services references for Administration of Blood and Blood Products shall be available on site.

5. Bone, Bone Products, Cells and Tissue

(1) Donation to Tissue Banks

(a) A NHMSF which collects tissues from patients for a tissue bank must do so under a written agreement with an approved tissue bank.
(b) The agreement must specify policies and procedures to be followed in accordance with applicable provincial and national standards and the American Associations of Tissue Banks (e.g. packaging, labelling, transfer).
(c) Donations of tissue will be an integral part of the consent and preoperative teaching of patients who are prospective donors.

(2) Use of Allogenic Bone, Bone Products, Cells and Tissues in NHMSFs

(a) A NHMSF must only use allogenic bone, bone products, and tissues acquired from sources reviewed and deemed acceptable by Tissue Bank Manitoba.

(b) The NHMSF must document compliance with all shipping, transportation and timing arrangements necessary to maintain the integrity and safety of all products received for use in patients.
(c) Documentation in the health record and a central log for transplanted tissues must include all information necessary for traceability.
(d) Patients must be given written information indicating they received an allogenic tissue or product.
(e) All products must be used only once and must not be reprocessed, refrozen or repackaged.
(f) All unused tissue and product must be disposed as bio-hazardous waste.

(3) The following references should be available on-site:

(a) Guidance Document: Basic Safety Requirements for Human Cells, Tissue and Organs for Transplantation – Health Canada, January 2003
(b) Tissue Bank Manitoba Policies, Procedures and Standards
(c) Cells, Tissues, & Organs for Transplantation & Assisted Reproduction: General Requirements – CAN/CSA-Z900.21-03
(d) Tissues for Transplantation – CAN/CSA-Z900.2.2-03
(e) Ocular Tissues for Transplantation – CAN/CSA-Z900.2.4-03

E. Safety Standards

(1) Facilities must meet with all Manitoba provincial or sanitary, safety, building and fire regulations.

(2) Smoking is prohibited as per Manitoba Provincial Regulations.

(3) Combustible materials must be handled in the approved manner that conforms to Manitoba regulations.

(4) Volatile supplies (e.g. oxygen) must be stored in accordance with Manitoba Workplace Safety and Health Regulations.

(5) Approved fire extinguishers must be in place and inspected routinely.

(6) Appropriate safety measures must be implemented when electrocautery is in use to prevent interference with other equipment or adverse patient events.

(7) The operating room and recovery room staff must be trained and current in BLS /ACLS.

(8) Facilities must have documented plans for emergencies including;

(a) fire
(b) power loss
(c) equipment failure
(d) over-sedation
(e) cardiopulmonary arrest
(f) anaphylaxis
(g) malignant hyperthermia
(h) unauthorized intruder
(i) Emergency Transfer to Hospital

(9) Facilities must comply with Workplace Safety & Health Regulations. Workplace Hazardous Material Information System (WHMIS) is included in this regulation and each facility must maintain a WHMIS manual.

F. Patient Care

1. Pre-operative Assessment

a. Patient Selection

(1) All patients must be assigned an American Society of Anesthesiologists (ASA) patient status (PS) classification by an anesthesia provider. Only patients screened for ASA I, II and III will have procedures performed in an NHMSF.

The full classification includes:

(a) ASA I – a normal healthy patient
(b) ASA II – a patient with mild systemic disease
(c) ASA III – a patient with severe systemic disease limiting activity, but not incapacitating
(d) ASA IV – a patient with incapacitating systemic disease that is a constant threat to life
(e) ASA V – a moribund patient not expected to live 24 hours with or without operation

(2) Special consideration must be given to prevent exposure of patients with latex allergy.

b. Patient Evaluation

(1) History and physical within 90 days of the proposed procedure. The history and physical will be accompanied by laboratory and diagnostic imaging investigations as indicated by the patient's medical status, drug therapy or the nature of the proposed procedure. All allergies must be documented with special note of latex allergy. A list of current medications must be included.

(2) Pre- anesthetic assessment to include:

(a) a review of the patient's clinical record including all diagnostic tests
(b) a medical interview with the patient
(c) a physical examination relative to anesthetic aspects of care
(d) a review of any pertinent medical consultations as required for peri-operative care
(e) orders for any pre-operative medications
(f) review of medications and allergies (note latex allergy)

c. Informed Consent

(1) Definitions:

(a) Informed Consent – a PROCESS involving dialogue, understanding and trust between the patient or Substitute Decision-Maker and the Responsible Party. Signing of the Consent Form only indicates that the PROCESS took place.

(b) Responsible Party – An approved physician with privileges within the NHMSF, who is responsible for the actual conduct of, or carrying out of, the proposed treatment(s), procedure(s), or investigation(s).

(c) Substitute Decision-Maker – A third party identified to participate in decision making on behalf of a patient who lacks Decision-Making Capacity, concerning a proposed procedure(s), treatment(s), or investigation(s). The task of a Substitute Decision-Maker is to faithfully represent the known preferences or, if the preferences are not known, the best interests of the incapable patient.

(d) Decision Making Capacity includes:

(e) ability to understand the information and to make a decision about the proposed course of action;

(f) ability to understand the nature and the anticipated effect(s) of the proposed procedure(s), treatment(s), or investigation(s); and

(g) ability to understand the alternatives and risks, including the consequence of not proceeding with the proposed course of action.

(h) The Responsible Party shall assess and determine if a patient has Decision-Making Capacity.

(i) Witness – someone other than the person obtaining the Informed Consent.

(j) Witnessing the Informed Consent indicates only that the Witness observed the patient or substitute decision maker provide the consent; it is not an indication that the witness has observed that Informed Consent was obtained. In elective situations, the Responsible Party should not be the witness.

(2) The Responsible Party must:

(a) complete the PROCESS;

(b) sign the Informed Consent Form; and

(c) document in the facility clinical record or the record in the Responsible Party's private office the details of the discussion.

(3) The Manager in charge (or equivalent), nurse in charge, or nurse responsible for care must ensure that the completed Consent Form is on the clinical record prior to administration of pre-procedure sedatives.

(4) What are the requirements for obtaining Informed Consent?

(a) Patient must have Decision-Making Capacity.

(b) Consent must be obtained prior to pre-procedure sedation.

(c) Preferably consent should not be obtained in the preoperative holding area.

(d) Disclosure of information as follows:

(i) As much as a reasonable person would want to know in order to make a decision about the proposed course of action, or information that if omitted, may result in a different decision.

(ii) Must be provided in a manner that is understood by the patient or Substitute Decision-Maker. Interpreters may be utilized as required.

(iii) Includes the following related to the procedure(s) treatments(s), or investigation(s):

- Name;
- Expected benefits;
- Material or significant risks;

- Likely consequences of not having the procedure(s), treatment(s), or investigation(s); and
- Answers to any questions from patient or Substitute Decision-Maker.

(iv) Based on the procedure(s), treatment(s), or investigation(s) being done, the information about the following may also need to be disclosed:

- Information required for consent for administration of blood/blood products; and
- Information required for consent to draw blood for testing of transmissible infection in the event that a health care provider experiences significant exposure to body fluids.

(v) The mere possibility of a complication does not mean that it has to be disclosed, however if its occurrence may result in serious consequences, such as paralysis, permanent disability or death, then it is regarded as a material risk.

(vi) Questions that may serve as guidelines include:

- How much information would an average reasonable person expect to be told?
- Would an average reasonable person give consent in the same situation?
- Would any significant detail, not mentioned, lead to a different decision?

d. Correct Site

(1) The facility must have a process to verify the correct patient, the correct surgical site and the correct procedure. This process must be documented and include:

(a) Pre-operative identification/confirmation process

(b) Marking of the operative site by the surgeon in the pre-operative holding area. The mark must be visible after the patient has been prepped and draped.

(c) A time out must occur immediately prior to beginning the procedure. The time out, led by the surgeon, must consist of active communication among the surgical team. The procedure must not begin until any questions or concerns are resolved.

2. Intra-Operative Management: Anesthesia & IV Sedation

(1) Monitoring guidelines apply to all patients receiving general anesthesia, regional anesthesia, intravenous sedation or retrobulbar anesthesia.

(2) The anesthesia provider must maintain current certification in Advanced Cardiac Life Support (ACLS) as specified by the Heart and Stroke Foundation of Canada.

(3) The anesthesia provider must remain with the patient at all times throughout the conduct of anesthesia and transfer of the patient to the Post Anesthesia Care Unit.

(4) IV sedation must only be administered or supervised by a physician who has completed training in the administration and monitoring of IV sedation. In the absence of an anesthesia provider, a second individual (either a nurse or a physician) with training in the monitoring of IV sedation must be present during the procedure. The following skills are required:

(a) Assessing and maintaining a patent airway
(b) Monitoring vital signs
(c) Venipuncture
(d) Completion of appropriate records
(e) Administration of medication
(f) BLS as per the Heart and Stroke Foundation of Canada (ACLS is recommended)

Patients receiving IV sedation must be continuously monitored for airway patency as well as pulse oximetry and regular blood pressure monitoring.

(5) Continuous monitoring of patients undergoing general anesthesia or major regional block must include:

(a) Visualization of some portion of the patient under appropriate lighting
(b) Pulse oximetry with audible signal recognition
(c) Capnography, when endotracheal tubes or laryngeal masks are inserted
(d) Blood pressure monitoring
(e) Electrocardiography with audible signal recognition
(f) Agent-specific anesthetic gas monitor, when inhalation anesthetics are used
(g) Peripheral nerve stimulator when neuromuscular blocking agents are used

(6) Monitoring of patients receiving retrobulbar anesthesia must include visualization of some portion of the patient under appropriate lighting, pulse oximetry and intermittent blood pressure monitoring.

(7) Additional items that must be immediately available include:

(a) Stethoscope
(b) An alternate source of oxygen
(c) Oropharyngeal airways
(d) A means of delivering positive pressure oxygen such as a self-inflating bag - valve device
(e) An emergency resuscitation cart that includes:
  (i) a cardiac monitor with defibrillator
  (ii) a device to measure patient temperature
  (iii) endotracheal tubes, laryngeal masks, stylets, oropharyngeal airways, face masks of various sizes, two laryngoscopes with a variety of sizes of laryngoscope blades and Magill forceps
  (iv) IV supplies, syringes, needles, ECG leads, etc.
  (v) cricothyrotomy kit
  (vi) a backboard for BLS
  (vii) drugs as listed in (Appendix C)

3. Intra-Operative Management: Surgical

(1) Operating room standards must be observed in regard to surgical asepsis. The surgeon is responsible for the maintenance of these standards, the post operative care of the surgical site and the care of the patient after discharge from the Post Anesthesia Care Unit.

(2) All tissues removed during a procedure must be sent for pathological examination unless specifically excluded by written policy. The specimen label and requisition for pathological examination must include:

(a) the patient name
(b) clinical record and PHIN numbers
(c) identity of the specimen with the site from which it is taken
(d) date and time collected
(e) name of the surgeon

(3) The process for the tracking of specimens sent to pathology must include the following key elements:

(a) a log of all specimens collected that includes the date and time collected, patient name and clinical record number as well as PHIN number;
(b) the date and time transferred to the laboratory and the name of the person releasing the specimens;
(c) the date the pathology report received by the facility.

4. Post Anesthesia Care Unit (PACU)

(1) An area must be provided for the patients' safe emergence from anesthesia.

(2) An anesthesia provider must accompany the patient to the PACU in order to provide the PACU staff with pertinent intra-operative information as well as written orders for post anesthesia care.

(3) The anesthesia provider or nurse must remain in continuous attendance of the patient.

(4) Heart rate, blood pressure, oxygen saturation by pulse oximetry, color, level of consciousness, respiratory rate and quality as well as activity must be monitored and documented at regular intervals throughout the recovery period until such a time as the patient meets the discharge criteria from the PACU. Each facility must have a policy describing discharge criteria.

(5) ECG monitoring equipment, suction, oxygen, a bag- valve-mask device, a thermometer, intravenous supplies, medication and medical/surgical supplies must be readily available.

(6) A resuscitation cart must be readily available.

(7) An anesthesia provider must remain on site until all patients have been discharged from the PACU.

5. Discharge of Patients Post Operatively

(1) Each facility must have a discharge policy. A written discharge order by the attending physician is required.

(2) Patients must be advised prior to surgery that a responsible adult is required to accompany them upon discharge. Should the patient fail to meet these criteria, the

planned procedure will be performed at the discretion of the physicians involved. Cancellation of the proposed procedure must be considered.

(3) Verbal and written discharge instructions must be reviewed with the patient and accompanying responsible adult. The patient must be instructed not to operate a motor vehicle or hazardous equipment for 24 hours after anesthesia. The patient must be instructed to have a responsible adult present for 24 hours post procedure.

(4) The patient and responsible accompanying adult must be instructed on how to access emergency care if necessary. They must also be instructed to notify the facility should the patient require unexpected admission to hospital within 10 days of treatment at the facility.

G. Documentation / Records

Each NHMSF must have a process for the documentation, storage and retrieval of all necessary patient information that complies with *PHIA* (*Personal Health Information Act*).

1. Medical Records

(1) The facility must be responsible to maintain medical records on all patients undergoing procedures within the NHMSF.

(2) The clinical record originates with the initial visit related to the current procedure to be performed. Medical records from previous procedures performed at the facility must be readily available.

(3) The clinical record must include the following:

- (a) Signed informed consent for the procedure and anesthesia
- (b) Pre-operative assessment and investigations, medical history, and physical examination that includes:
  - (i) a presumptive diagnosis
  - (ii) current medication list
  - (iii) weight
  - (iv) allergies
  - (v) laboratory results
- (c) Pre-operative checklist that includes documentation of correct patient, correct site, and correct procedure process
- (d) Anesthetic record that includes:
  - (i) pre-anesthetic assessment
  - (ii) all drugs administered including dose, time and route
  - (iii) fluids administered
  - (iv) measurable/estimated fluid loss
  - (v) recording of monitored vital signs every 5 minutes
  - (vi) complications or incidents where applicable
  - (vii) names of anesthesia provider and surgeon
  - (viii) anesthetic start and stop times
- (e) Intra-operative record that includes:
  - (i) documentation that a time out has occurred
  - (ii) pre-operative diagnosis
  - (iii) procedure performed
  - (iv) names of surgeon, anesthesia provider and all other personnel present
  - (v) appropriate information including: instrument count, tourniquet time, solutions used, implants used, patient position, surgical time, tissues removed and disposition etc
- (f) Post-anesthetic record that includes:
  - (i) date and time of admission
  - (ii) initial and ongoing measurements of blood pressure, pulse, respirations, temperature, level of consciousness, oximetry and general status
  - (iii) any medications administered, including dose, time, route, reason and effects
  - (iv) any treatment administered and outcome

(v) objective scoring measurement for discharge
(vi) names of PACU personnel

(g) Documentation of discharge process as reflected in Section F.5. (Discharge of Patients Post Operatively) of this document.

(4) The operative report must be generated on the date of the procedure by the surgeon. Copies of the operative report and pathology report must be retained on the patient's clinical record.

(5) The clinical record is the property of the facility and the responsibility of the Medical Director.

2. Storage and Retention

(1) Each facility must retain medical records, operating room logs and adverse event reports in a safe, secure manner to protect patient confidentiality.

(2) Such records must be retained for at least 10 years from the date of last service to the patient, or in the case of minors, to the date the patient is 18 years old plus 10 years.

3. Annual Report to College

(1) The Medical Director of each facility must provide an annual report to the College that includes (Appendix D):

(a) The number of each type of procedure performed.
(b) The names of all physicians with privileges in the facility, which procedures each physician performs, their hospital affiliation and ACLS status.
(c) The name of any physicians whose privileges in the facility were not renewed or were reduced and the reason for it.
(d) Audit reports including audits of infections and complications as well as adverse events.
(e) The types and number of anesthetics administered.

4. Adverse Events

(1) There must be an internal process to document and investigate adverse events. The report must include the following:

(a) Name, age, sex of patient involved
(b) Name(s) of witness(es)
(c) Date and type of procedure
(d) Date and time of adverse event
(e) Nature of adverse event and treatment rendered
(f) Analysis of reasons for the adverse event
(g) Outcome
(h) A process to document corrective action taken if applicable

(2) A copy of all reports must be kept in a separate file that is reviewed at least annually by the Medical Director. A summary report must be provided to the Committee with the Annual report.

5. Reportable Adverse Events

(1) The Standards Committee will collaborate with NHMSF to ensure that reportable adverse events are reviewed with the intent of enhancing patient safety.

(2) The Medical Director must notify the CPSM Standards Department within one working day after the discovery of any adverse event such as:

- (a) Deaths within the facility or within 10 days of the procedure. In the event of a death within the facility, the Medical Examiner must be notified prior to moving the body or removal of any lines or tubes from the body.
- (b) Transfers from the facility to a hospital regardless of whether or not the patient was admitted.
- (c) Unexpected admission to hospital within 10 days of a procedure or anesthetic performed in the facility. The Deputy Registrar may determine that written notification is not required if the reason for admission is not related to the services provided in the facility.
- (d) Unusual frequency or type of infections among patients treated in the facility. CPSM will collaborate with the NHMSF when frequent or unusual infections are identified to assist in the management of the event.
- (e) Any procedure performed on the wrong patient, site or side.

(3) Within two weeks of notification a written report must follow. The report must include:

- (a) Completed reportable adverse event form signed by the Medical Director.
- (b) A copy of the facility clinical record.
- (c) Narrative summary describing the adverse event by the most involved physician(s).
- (d) Any corrective action taken to date.

(4) The Deputy Registrar may review the circumstances of the event with the Medical Director. Further recommendations may be made to assist the NHMSF to enhance patient safety.

H. Infection Control / Prevention and Monitoring

1. General

(1) Routine Practices must be incorporated into everyday patient care. NHMSF policy must provide for education of every care provider in the principles of Routine Practices, provision of adequate equipment to implement them, and a means by which compliance with practice can be monitored and audited.

All personnel must understand and adhere to "Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care, 1999". (This guideline is available online at http://www.hc-sc.gc.ca/hpb/lcdc). These precautions include:

(a) Appropriate hand-washing practices (reference Hand Washing, Cleaning, Disinfection and Sterilization in Health Care; Canada Communicable Disease Report. 1998; 24S8:1-55 (This guideline is available online at http://www.hcsc.gc.ca/hpb/lcdc/publicat/ccdr/98pdf/cdr24s8e.pdf).
(b) The proper use of personal protective equipment (PPE) such as gowns, gloves, eye/face protection, and masks.
(c) The proper use, storage and disposal of sharp devices and biological waste.
(d) Use of hospital grade approved disinfectant to clean the environment and appropriate containment of soiled items.

(2) In situations requiring additional precautions, these precautions must be instituted as soon as indicated by triggering mechanisms such as diagnosis, symptoms of infection, laboratory information, or assessment of risk factors.

(3) The facility is responsible for ensuring that appropriate precautions are taken for any patients known to be incubating, colonized or infected with an infectious agent.

(4) All personnel (physicians, nurses, technologists/technicians, students, volunteers and others) are responsible for complying with Routine Practices and Additional Precautions and for tactfully calling observed infractions to the attention of all offenders. There are no hierarchical exceptions to precautions, and everyone has a responsibility to monitor his or her own practice as well as the practice of other care providers. There are no exceptions, and all should teach by example.

(5) All efforts must be made to prevent the transmission and acquisition of infections at the facility. Facilities must have mechanisms in place to address processes during times of communicable disease outbreaks.

2. Occupational Health/Immunization

(1) The Workplace Safety and Health Act and Regulations will apply. Copies of the Act and Regulations are available on-line at www.safemanitoba.com.

(2) All personnel, including physicians, shall have their immunization status reviewed and documented at the time they commence work at the facility and periodically thereafter.

(3) Immunization should be offered if immune status is unknown.

(4) Immunization standards for Non Hospital Medical/Surgical Facility staff shall follow the Canadian Immunization Guide at www.phac-aspc.gc.ca.

(5) There must be a policy and procedure for the management of significant exposures (e.g. needle stick injuries). Health Canada Infection Control Guideline: Prevention and Control of Occupational Infections in Health Care, 2002; Pages 157-179.

(6) All personnel with open lesions, including physician, nursing and support staff, must seek medical attention prior to performing or assisting with invasive procedures, for protection of both the staff member and the patient.

(7) Consultation with a specialist in infectious disease must be obtained prior to workers with bloodborne pathogens starting work in the facility. "Health care workers who perform exposure-prone procedures have an ethical obligation to know their serologic status for hepatitis B virus (HBV), human immunodeficiency virus (HIV) or hepatitis C virus (HCV) and to follow the recommendations in 'Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens, CCDR 1998; 24S4:1-25' (This document is available on line at http://www.hc-sc.gc.ca/hpb/lcdc/public/ccdr/98vol24/24s4/ index.html").

(8) Sharps must be placed in clearly labeled puncture resistant containers, ~~and~~ transported and disposed of in accordance with local regulations.

(9) Sharps containers must not be over-filled, and one container must never be emptied into another.

(10) Staff must not consume food or beverages in patient treatment areas.

3. General Infection Prevention Measures

(1) Personnel must be familiar with and adhere to aseptic techniques. Training in aseptic technique by a person approved by the Medical Director must be offered to all new employees involved in direct patient care.

(2) There must be at least one hands-free sink for hand scrubbing and hand washing that must not be used for any other purpose. It must be of sufficient depth to prevent back splashing.

(3) A sufficient supply of cloth or disposable towels must be available so that a fresh towel can be used after each hand washing. Common towels are prohibited.

(4) All personnel who scrub for procedures must follow an approved hand scrub protocol prior to each operating procedure. Anesthesia providers and all circulating personnel must hand wash with an antimicrobial soap prior to each procedure. (Reference (1) Centers for Disease Control and Prevention (CDC): Guideline for Prevention of Surgical Site Infection (SSI) 1999 and (2) Health Canada Infection Control Guideline: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care, 1999.)

(5) An antimicrobial preparation must be used for all surgical scrubs followed by sterile towels to dry hands as required prior to donning sterile gloves.

(6) An antimicrobial skin preparation must be applied prior to performing an invasive procedure.

(7) Containers of soaps, antimicrobials, and other solutions must not be topped up. If containers need to be reused, they must be emptied, cleaned, and dried before re-use. A cartridge system that cannot be topped up is preferred.

(8) Operating room personnel should adhere to a dress code consistent with the Operating Room Nurses Association of Canada standards.

(9) The use of multi-dose vials is strongly discouraged. If they are used, care must be taken not to contaminate the contents of the vial. The rubber diaphragm must be wiped with alcohol, and a new sterile needle and syringe must be used each time the vial is entered. The date the vial is first used must be recorded on the vial. The opened vial should be discarded within a period recommended by the manufacturer or within one month.

(10) Drugs must never be delivered from a common IV bag, IV tubing or syringe to more than one patient.

(11) Air flow and quality in operating suites must be monitored and maintained according to standards applicable for the type of surgical procedures performed.

NOTE: Consideration must be given to the type of surgery planned in the facility at the current time and in the future when determining the air exchanges required. The recommended air exchange is in the range of 15-20 air exchanges per hour. However, in the event the facility will be doing superficial, no implant, minor surgery procedures, the air exchanges could be in the 12-15 range per hour. The facility must have on record, a dated engineering report that states the actual air exchange for the purpose of the current accreditation and infection control safety. The Centers for Disease Control and Prevention Guideline for Prevention of Surgical Site Infection, 1999; Pages 260-267" also recommends a minimum of 3 exchanges/hour of fresh air and the filtering of all incoming air through a filter of >90% efficiency, and may be found at www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.

(12) Adequate hand washing sinks must be appropriately located throughout the facility. Waterless, alcohol based antiseptic hand agents are an acceptable alternative to soap and water, if there is no visible soiling.

(13) Hand hygiene must be performed between patients, after removal of gloves and after contact with any contaminated objects.

(14) Masks, eye protection or face shields must be worn for protection of mucous membranes of the eyes, nose and mouth during procedures likely to generate splashes or sprays of blood, body fluids, secretions or excretions.

(15) Clean non-sterile gloves must be worn:

(a) for contact with blood, body fluids, secretions and excretions, mucous membranes, draining wounds or non-intact skin (open skin lesions or exudative rash);

(b) when handling items visibly soiled with blood, body fluids, secretions or excretions;
(c) when the healthcare worker has open lesions on the hands.

(16) Gloves are to be removed and hand hygiene performed immediately after completion of care or procedure; at point of use and before touching clean environment surfaces.

(17) A designated person responsible for the maintenance and enforcement of infection prevention and control and occupational health & safety standards in the facility is recommended.

(18) Traffic in patient care areas and particularly in operating room suites must be restricted to authorized personnel.

(19) During procedures, doors to the operating room suites must be kept closed, except for entry and exit by operating room personnel

(20) Personnel must not eat or drink in any area where direct patient care is provided or where reprocessing occurs.

(21) Virus filters or a clean anesthetic circuit must be used for each patient.

(22) Bed linens and pillow covers must be changed between patients. Beds and stretchers must be wiped down with a hospital grade disinfectant between patients.

(23) Patient care items such as K-basins, thermometers, etc., must not be used between patients unless reprocessed according to the manufacturer's guidelines. Other items, such as cups, should be disposable.

(24) Drinking water for personnel and patient use must be obtained from a clean sink or dispensing apparatus.

(25) Medications that require refrigeration must not be stored in a common fridge with food or beverages.

(26) No animals other than service animals, aquariums, water fountains or indoor gardens should be allowed in the facility.

(27) The facility must effectively be protected against the entrance of insects, animals, or the elements by self closing doors, closed windows, screens, controlled air currents, or other effective means.

4. Additional Precautions

Consideration must be given to re-scheduling patients requiring additional precautions, or providing the service within a hospital setting.

(1) Airborne Transmission Precautions

(a) Patients with known or suspected infectious tuberculosis, measles, varicella or disseminated varicella zoster should be placed directly in a single examination room with the door remaining closed.
(b) Those patients must wear a surgical/procedure mask while in the facility.
(c) High efficiency dust/mist masks (e.g. N95 Respirator Masks) must be worn by all healthcare workers who enter the examination room of a patient with known or suspected infectious tuberculosis.
(d) High efficiency dust/mist masks (e.g. N95 Respirator Masks) must be worn by non-immune healthcare workers who absolutely must enter the examination room of a patient with varicella, disseminated zoster or measles.

(2) Droplet Transmission Precautions

(a) Patients with known or suspected meningococcal infection, rubella, mumps, pertussis, influenza, SARS should be placed in a single examination room. If this is not possible, the patient must maintain a minimum one meter spatial separation from other patients.
(b) Surgical/procedure masks should be worn by all healthcare workers that must come within one meter of the patient.
(c) The patient must wear a surgical/procedure mask while in the facility.

(3) Contact Transmission Precautions

(a) Patients with known or suspected diarrhea, extensive skin or wound infection not contained by dressings, herpes simplex-disseminated, scabies (extensive or Norwegian/crusted), and Antibiotic Resistant Organisms (ARO) should be placed in a single examination room. If this is not possible, a spatial separation of one meter must be maintained between patients.
(b) Gloves must be worn when entering the patient's room or designated examination space. Gowns must be donned before providing direct patient care.
(c) Gloves must be removed before leaving the patient's room or designated examination space.
(d) Hand hygiene must be performed after removing gloves.
(e) Equipment and surfaces in direct contact with the patient or infective materials must be cleaned before the room is used by another patient.

5. Patient Care Practices

(1) There must be a mechanism to record all adverse events including, but not limited to: breaks in sterile technique, significant exposures to blood and body fluids, needle stick injuries, inadvertent use of improperly sterilized equipment, and related breaches of policy and deviations from standard procedure.

(2) There must be a mechanism of surveillance and review of post-operative infection rates, and a record of consultations undertaken as a result.

(3) The prevention of nosocomial infection should be a continuing education subject for all personnel.

(4) The Medical Director is ultimately responsible to correct any deficiencies and to seek expert advice when needed.

(5) NHMSF contacts of newly confirmed infectious pulmonary tuberculosis patients must be referred to Regional Public Health authorities.

6. Reprocessing (Cleaning, Disinfection, and Sterilization)

a. General

(1) There must be no re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.

(2) All critical medical equipment must be sterilized before each patient use (medical equipment that enters sterile tissues, including the vascular system.)

(3) All semi-critical medical equipment must receive a minimum of high level disinfection before each patient use (medical equipment that comes in contact with non-intact skin or mucous membranes).

(4) There must be current written policies and procedures on all steps of reprocessing readily available for staff.

(5) There must be written information from the manufacturer on the safe and appropriate reprocessing of this medical equipment, included in the written procedures.

(6) There must be a designated reprocessing area that is separate from patient care areas.

(7) Hand hygiene stations for staff must be readily available in the reprocessing area (hand washing sinks and/or alcohol dispensers).

(8) Clean Personal Protective Equipment (PPE) must be worn by staff when reprocessing. (Eye protection or face shields, masks, gowns, gloves.)

(9) There must be a trained designated staff member acceptable to the Medical Director responsible for reprocessing.

(10) There must be a documented training process for staff performing reprocessing.

b. Cleaning

(1) The process for cleaning must include written protocols for disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection, reassembly and wrapping.

(2) Full PPE must be worn for handling and cleaning contaminated equipment/devices.

(3) The process used for cleaning should include the following steps:

(a) Disassembly

(i) Unless otherwise recommended by the manufacturer, equipment/devices must be disassembled prior to cleaning.

(ii) The manufacturer's recommendations must be followed when disassembling medical equipment/devices prior to washing.

(b) Sorting and soaking

(i) Cleaning detergent and solutions must be used according to the manufacturer's written instructions.

(ii) Sharps and/or delicate equipment/devices should be segregated to prevent injury to personnel and damage to the equipment/device.

(iii) Equipment/devices should be sorted into groups of like products requiring the same processes.

(iv) Equipment/devices should be soaked in an approved instrument soaking solution to prevent drying of soil, making cleaning easier. Saline should not be used as a soaking solution as it damages some medical equipment/devices.

(v) Cleaning must always be performed as soon as possible after use to prevent bio-burden from hardening.

(vi) Cleaning with detergent or enzymatic solutions and clean water must always precede high-level disinfection or sterilization processes.

(vii) Detergent-based products, including those containing enzymes, may be used as part of the soaking process. The detergents (including enzymatic detergents) must be appropriate to the equipment/device being cleaned.

(viii) Detergent or enzymatic cleaning solutions must be discarded after each use.

(c) Physical removal of organic material

(i) Immersible items must be completely submerged during the cleaning process in order to minimize aerosolization of microorganisms and assist in cleaning.

(ii) Gross soil may be removed using tools such as brushes and/or cloths.

(iii) After gross soil has been removed manual or mechanical cleaning such as a washer-disinfector or ultrasonic cleaning, must be employed.

(iv) Washer-disinfectors are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel. Washer-disinfectors must meet the requirements of the CSA. Manufacturer's instructions must be followed for the use and regular maintenance, cleaning and calibration of the washer-disinfector. Washer-disinfectors may be used for low level disinfection. Washer-disinfectors are not to be used for high level disinfection.

(v) Ultrasonic washers are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean. Manufacturer's instructions must be followed for use of the ultrasonic cleaner. The ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled.

(vi) If manual cleaning is performed, physical removal of soil must occur under the water level to minimize splashing.

(vii) Tools used to assist in cleaning, such as brushes, must be disposable or thoroughly cleaned and must be high level disinfected or sterilized between uses.

(viii) There must be documented preventative maintenance of the automatic washer as specified by the manufacturer.

(d) Rinsing following cleaning is necessary as residual detergent may neutralize the disinfectant.
   (i) All equipment/devices must be thoroughly rinsed after cleaning with water to remove residues which might react with the disinfectant/sterilant.
   (ii) The final rinse for equipment/devices containing lumens must be performed with commercially prepared sterile water (note: distilled water is not necessarily sterile).

(e) Drying is an important step to prevent dilution of chemical disinfectants which may render them ineffective and prevents microbial growth.
   (i) The manufacturer's instructions must be followed for drying of the equipment/device.
   (ii) Equipment/devices may be air-dried or dried by hand with a clean, lint-free towel.
   (iii) Stainless steel equipment/devices should be dried immediately after rinsing to prevent spotting.

(f) Inspection
   (i) All equipment/devices must be visually inspected once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device (e.g. cracks, defects, adhesive failures).
   (ii) Cleaning must be repeated on any item that does not appear clean.
   (iii) The manufacturer's guidelines must be followed for lubrication.
   (iv) Equipment/devices must not be reassembled prior to disinfection/sterilization.

(g) Wrapping
   (i) Equipment/devices to be sterilized require wrapping prior to sterilization (except for flash sterilization).
   (ii) Materials used for wrapping must be prepared in a manner that will allow adequate air removal, steam penetration and evacuation.

(h) Practice audits
   (i) Cleaning processes must be audited on a regular basis.
   (ii) A quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.

(i) There must be a designated area for soiled supplies. This area must be physically separated from patient care areas and from areas housing clean and sterile supplies.

(j) The soiled area should have:
   (i) Adequate counter space to receive soiled supplies.
   (ii) A double utility sink to rinse and clean soiled items.
   (iii) A flushing device for the disposal of body fluid wastes.

(k) The clean area must have adequate counter space for receiving washed equipment for storage or wrapping.

(l) There should be a sink dedicated to hand washing or alcohol hand rub available in the reprocessing area.

c. Disinfection of Reusable Medical Devices

(1) Disinfection of medical equipment/devices falls into two major categories – low level disinfection and high level disinfection.

(2) There are two major methods of disinfection used in health care settings – liquid chemicals and pasteurization.

(3) All disinfectants must have a Drug Identification Number (DIN) from Health Canada.

(4) Low Level Disinfection (LLD) eliminates vegetative ("live") bacteria, some fungi and enveloped viruses. LLD is used for noncritical medical equipment/devices and some environmental surfaces. Low level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, some quaternary ammonium compounds (QUATS), phenolics and diluted sodium hypochlorite (e.g. bleach) solutions. LLD is performed after the equipment/device is thoroughly cleaned and rinsed. The container used for disinfection must be washed, rinsed and dried when the solution is changed. Refer to Appendix G for chemical products that may be used to achieve low level disinfection.

(5) High Level Disinfection (HLD) eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria (e.g. Tuberculosis) and non-enveloped viruses. HLD is used for semi critical medical equipment/devices. High level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Pasteurization also achieves high level disinfection. HLD is performed after the equipment/device is thoroughly cleaned and rinsed. Refer to Appendix I for chemical products that may be used to achieve high level disinfection.

(a) Noncritical medical equipment/devices are to be decontaminated using a Low Level Disinfectant.

(b) Semi critical medical equipment/devices must be decontaminated using, at a minimum, High Level Disinfection. Sterilization is the preferred method of decontamination.

(c) Noncritical and semi critical medical equipment/devices that are owned by the client and reused by a single client in their home do not require disinfection between uses provided that they are adequately cleaned prior to reuse.
See Section 6.b.(3), "Disassembling and Cleaning Reusable Medical Equipment/Devices" for cleaning requirements.

(d) The chemical disinfectant used for disinfecting medical equipment/ devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.
The following should be considered when selecting a disinfectant for use in the health care setting:
  (i) Compatibility with equipment/device and surfaces to be disinfected;
  (ii) Compatibility with detergents, cleaning agents, and disinfection and/or sterilization processes;
  (iii) The intended end use of the equipment/devices to be disinfected;
  (iv) Personal and environmental safety.

(e) Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used.

(i) Manufacturer's recommendations for chemical disinfectants must be followed pertaining to:
- Use
- Contact time (NOTE: Where the manufacturer recommends a shorter contact time with a particular product than is required to achieve the desired level of disinfection/sterilization, an infection prevention and control specialist must be consulted for advice)
- Shelf life
- Storage
- Appropriate dilution
- Required PPE

(ii) If a disinfectant manufacturer is unable to provide compatibility information specific to a piece of medical equipment/device, information may be obtained from Health Canada's drug information website: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/dpd_index_e.html.

(f) The process of high level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.

(i) Chemical test strips should be used to determine whether an effective concentration of active ingredients is present despite repeated use and dilution.

(ii) The frequency of testing should be based on how frequently the solutions are used (i.e. test daily if used daily).

(iii) Chemical test strips must be checked each time a new package/bottle is opened to verify they are accurate, using positive (e.g. full strength disinfectant solution) and negative (e.g. tap water) controls. See manufacturer's recommendations for appropriate controls.

(iv) Test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date.

(v) A permanent record of processing must be completed and retained according to the policy of the facility. This record must include, but not be limited to, the identification of the equipment/device to be disinfected; date and time of the clinical procedure; concentration and contact time of the disinfectant used in each process; results of each inspection (and, for endoscopes, each leak test); result of each testing of the disinfectant; and the name of the person completing the reprocessing.

(vi) Disinfection practices must be audited on a regular basis and a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.

(vii) If manual disinfection is performed, the container used for disinfection must be kept covered during use, and washed, rinsed and dried when the solution is changed.

(viii) Rinsing of medical equipment/devices following chemical disinfection requires three separate rinses, using sterile water, and the rinse solutions must be changed after each process.

(h) The HLD product used must have a Drug Identification Number (DIN) from Health Canada.

(i) HLDs must be prepared and used correctly to achieve the manufacturer's recommended dilution and length of immersion required to attain HLD.

(j) When preparing HLD solutions, sources of extrinsic contamination (contaminated containers/preparation area) must be prevented.

(k) HLD concentration must be checked daily at a minimum with an appropriate chemical test strip; and must be discarded/changed if the concentration is less than the minimum effective concentration.

(l) There must be a log kept of dates when HLD is changed.

(m) Test strips must not be used past the expiry date listed on the container.

(n) There must be a quality control procedure for checking test strips each time a new bottle is opened and must be performed according to the manufacturer's recommendation.

(o) A log must be kept of the test strip results.

(p) All reprocessed equipment must be stored in a manner to keep it clean and dry.

(5) Pasteurization

(a) Pasteurization is a process of hot water disinfection (75°C for 30 minutes) which is accomplished through the use of automated pasteurizers or washer disinfectors. Semi critical medical equipment/devices suitable for pasteurization include equipment for respiratory therapy and anesthesia. Equipment/devices require thorough cleaning and rinsing prior to pasteurization. Advantages of pasteurization include:

(i) No toxicity

(ii) Rapid disinfection cycle

(iii) Moderate cost of machinery and upkeep

(b) Disadvantages of pasteurization include:

(i) It may cause splash burns

(ii) There is difficulty validating the effectiveness of the process

(iii) Pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes

(c) Manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated.

(d) The process must be monitored with mechanical temperature gauges and timing mechanisms for each load, with a paper printout record. Pasteurizing equipment must have, or be retrofitted for, mechanical paper printout. In addition:

(i) Water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;

(ii) Cycle time should be verified manually and recorded daily;

(iii) Calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;

(iv) Daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations;

(v) Following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil. Damaged equipment/devices should be handled according to facility procedures. Soiled equipment/devices should be reprocessed;

(vi) Following pasteurization, medical equipment/devices must be handled so as to prevent contamination. Equipment/devices must be transported directly from the pasteurizer to a clean area for drying, assembly and packaging.

(e) A preventive maintenance program for pasteurizing equipment must be implemented and documented.

(f) Following the pasteurizing cycle, medical equipment/devices must be thoroughly dried in a drying cabinet that is equipped with a HEPA filter and that is used exclusively for the drying of pasteurized equipment/devices. A preventive maintenance program for drying cabinets must be implemented and documented.

(g) A logbook of contents, temperature and time is to be maintained for pasteurizing equipment.

(h) If the pasteurizer produces printed records of the parameters of each cycle, these records must be retained in accordance with the facility's requirements.

d. Sterilization

(1) Sterilization is used on critical medical equipment/devices and, whenever possible, semi critical medical equipment/devices. The preferred method for heat-resistant equipment/devices is steam sterilization (pre-vacuum sterilizers are preferred)

(2) The sterilization process must be validated and documented with written policies and procedures.

(a) Policies and procedures must be established to ensure that the sterilization processes follow the principles of infection prevention and control as set out in Health Canada guidelines, CSA standards and best practices. All sterilization processes/equipment must follow the manufacturer's instructions for installation, operation and preventative maintenance of equipment.

(b) All sterilization processes must be thoroughly evaluated before being put into service, and at regular intervals thereafter.

(3) Flash sterilization must only be used in emergency situations and must never be used for implantable devices.

(4) A log must be kept of preventative maintenance performed on sterilization equipment.

(5) Equipment to be sterilized must be wrapped and secured in materials that allow sterilant penetration, and must be appropriate to the sterilization method and provide a barrier to contamination.

(6) For all sterilizers:

(a) All three of the following parameters must be completed to ensure that effective sterilization has been achieved. Test packs may be purchased for this purpose.

(i) Mechanical monitoring (e.g. time, temperature, pressure graphs);

(ii) Chemical monitoring – each pack must have external chemical indicators. In addition, it is recommended that both internal and external visible chemical indicators be used to detect penetration into the pack. The CSA recommends that "an internal chemical indicator shall be placed inside all packages. This indicator shall be placed in the area of the package least accessible to steam" or to the sterilizing agent, in order to verify that the sterilant has penetrated the package;

(iii) Biologic monitoring (e.g. spore-laden strips or vials) – include a biologic monitor each day a sterilizer is used. A biologic monitor must be used with each load if implantable equipment/devices are being sterilized. The recommended test microorganisms are:

- Geobacillus stearothermophilus (formerly Bacillus stearothermophilus) spores for sterilizers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as flash sterilizers;
- Bacillus atrophaeus (formerly Bacillus subtilis) spores for sterilizers that use dry heat or ethylene oxide;

(b) Staff performing the process must document the daily operation of the sterilizer. This documentation should be reviewed for each operation. Any malfunction should be noted and appropriate action taken.

(c) If biological monitor is positive, the load must be recalled and the equipment reprocessed before use.

(d) Autoclaves must be installed according to the manufacturer's instructions. Tabletop steam sterilizers are recommended for office settings.

(e) Filter systems should be tested for leakage.

(f) Gas sterilization units should be appropriately validated for such factors as gas concentration, temperature, and relative humidity.

(g) For sterilizers of the dynamic air removal type, three consecutive tests must also be conducted with the air detection test pack (Bowie-Dick) yielding uniform color change.

(h) Ethylene oxide is a designated substance under the Occupational Health & Safety Act:

(i) Facilities that use 10 kg. or more per year of ethylene oxide for sterilization must comply with guidelines from Environment Canada, specifically:

- Emissions of ethylene oxide must be reduced by 99% during the sterilization cycle by installing an emission control system;
- Emissions of ethylene oxide must be reduced by 95% during aeration;
- Eliminate liquid discharge to avoid releases of ethylene oxide to the local sewer system;
- Test emissions of ethylene oxide annually;
- Report annually to Environment Canada.

(ii) At the conclusion of a sterilization cycle and before the load is removed, the operator must check the recording chart printout to ensure that required parameters have been met. If the chart or printout indicates a failure of any parameter, the operator must follow the health care setting's applicable policies and procedures.

(iii) Medical devices sterilized with ethylene oxide must be thoroughly aerated prior to handling or use, according to the device manufacturer's recommendations. Reprocessing staff must not interrupt the aeration cycle to retrieve items for use.

(iv) Interruption of the aeration cycle to retrieve items for use must be documented as an adverse event.

(i) Dry heat sterilization must be rigidly monitored with each cycle due to differences in penetration with different items.

(7) A log must be kept of mechanical and chemical indicator results.

(8) If mechanical or chemical indicators suggest inadequate processing, the items must not be used.

(9) Sterilizers must be monitored with the appropriate biological indicator each day the sterilizer is used (with every load if sterilizing implantable devices).

(10) Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity.

(a) Following installation of a new sterilizer, the sterilizer must pass at least three consecutive cycles with the appropriate challenges (i.e. biological, chemical) placed in an empty sterilizer, as well as at least one cycle challenged with a full test load, before the sterilizer can be put into routine service.

(b) The sterilizer must not be approved for use if the biologic monitor yields a positive result on any of the tests.

(c) Sterilizers must be monitored with a test load in the following circumstances:

(i) After major repairs to an existing sterilizer;

(ii) When there has been construction or relocation in the area;

(iii) After unexplained sterility failures;

(iv) After changes in steam supply or delivery

(11) A quality control procedure must be performed and documented on all new biological indicator lots.

(12) A log must be kept of biological monitoring results.

(13) A log must be kept of all maintenance and interventions associated with a positive biological monitor.

(14) There must be a process in place that clearly identifies a non-reprocessed piece of equipment from one that has been reprocessed

(15) Critical equipment that is sterilized unwrapped must be used immediately and not stored.

(16) Semi-critical equipment sterilized unwrapped must be stored in a clean, dry area until use.

(17) Equipment must be cleaned and dried before an unwrapped sterilization cycle. Lumens must be flushed with sterile water prior to sterilization.

(18) Sterility of equipment must be maintained during removal from the sterilizer and transport to point of use. Sterilized wrapped goods must not be handled until cooled to maintain sterility.

(19) Appendix C is a list of Canada Standards Association documents which describe guidelines for sterilization. They should be consulted as necessary but do not necessarily constitute College standards. Copies can be obtained by contacting the Canadian Standards Association at: www.csa.ca.

(20) Outside shipping cartons and any corrugated cardboard containers must not be kept in the clean supply area. Unpacking of the cartons must not be carried out in the clean area or in the patient care areas.

e. Storage and Use of Reprocessed Medical Devices

(1) The sterile storage area must be well-ventilated and protected from dust, moisture, insects, and temperature (to avoid build-up of humidity) extremes.

(2) Sterility must be maintained until point of use. The shelf life of a sterile package is event related rather than time related. Event related shelf life is based on the concept that items that have been properly decontaminated, wrapped, sterilized, stored and handled will remain sterile indefinitely, unless the integrity of the package is compromised (i.e. open, wet, dirty).

(a) Medical equipment/devices purchased as sterile must be used before the expiration date if one is given.
(b) Sterile packages that lose their integrity must be re-sterilized prior to use.

(3) Reprocessed medical equipment/devices must be stored in a clean, dry location in a manner that minimizes contamination or damage.

(a) Equipment/devices must be handled in a manner that prevents recontamination of the item.
(b) Containers used for storage of clean equipment/devices should be moisture-resistant and cleanable (i.e. cardboard boxes must not be used).
(c) Store equipment/device in a clean, dry, dust-free area (closed shelves), 6" off floor level, and at least one meter away from debris, drains, moisture and vermin to prevent contamination.
(d) Store equipment/device in an area where it is not subject to tampering by unauthorized persons.
(e) Transport processed equipment/device in a manner that avoids contamination or damage to the equipment/device.

(4) At point of use, upon opening the reprocessed medical equipment/device, check for integrity of the packaging and the equipment/device; validate results of chemical monitors if present; and reassemble equipment/device if required.

(a) Provide education to those opening sterile items at point of use. Education should include inspection, interpretation of monitors and reassembly of equipment/devices.
(b) Validate results of chemical tape and internal monitors if present.
(c) Visually inspect the equipment/device for discoloration or soil. If present, remove from service and reprocess.
(d) Check for defective equipment/devices and remove from use.
(e) If sterile package has become damp or wet (e.g. high humidity), reprocessing may be required.
(f) Reassemble equipment/device if required.

7. Housekeeping and Waste Management

(1) The premises must be kept neat, clean, and free of waste material.

(2) Handling of waste material must comply with Regional waste handling requirements.

(3) Specifically trained housekeeping personnel should maintain an established housekeeping routine.

(4) Personnel must adhere to a written protocol for cleaning each operating room:

(a) between cases
(b) at the end of the day
(c) weekly
(d) monthly

(5) Wet mopping must be used. Dry dusting and dry mopping are not acceptable.

(6) Provisions must be made for proper laundering of linens and washable goods.

(7) Soiled linen must be placed in containers and handled as little as possible.

(8) Protective garments (e.g. impervious gowns and gloves) should be worn to sort soiled linen.

(9) All patient care linen must be removed from the operating room after each case.

(10) Clean linen must be covered and stored separate and apart from soiled linen.

(11) Garbage must be collected, contained, stored, and disposed so as to prevent disease transmission.

(12) For further information, refer to: Canadian Communicable Disease Report: Hand Washing, Cleaning, Disinfection and Sterilization in Health Care.

I. Endoscopy

The document prepared by the Endoscopy Working Group of the Infection Control Subcommittee of the Manitoba Advisory Committee on Infectious Diseases forms the basis for these standards. (Appendix F)

Non-immersible endoscopes must be replaced because they are very difficult to clean and disinfect.

Endoscopes that cannot withstand the processes described in these guidelines because of age, design or damage must not be used.

There are a number of good consensus guidelines available, which discuss in detail infectious agents that can be transmitted by endoscopy, appropriate procedures for cleaning, reprocessing, and discussion about disinfection issues and agents.

1. Personnel

Practices that must be followed include:

(1) All personnel should be immunized for Hepatitis B.

(2) Bronchoscopy personnel should be monitored by Public Health following an exposure to tuberculosis.

(3) Health care workers who have respiratory problems (i.e. asthma, latex or chemical allergies) should be assessed by a physician prior to working in the area.

(4) Concentration of glutaraldehyde fumes, if used, should never exceed limits set by the Workplace Safety & Health Division, Manitoba Labour. Irritation can be minimized with covered containers and by using disinfectants in a well-ventilated area.

(5) Eye protection and surgical masks or face shields should be worn to prevent contact with splashes during the cleaning procedure and disinfection/sterilization process.

(6) Moisture-resistant gowns should be worn to prevent contamination of personnel due to splashes of blood or other body fluids or injury due to chemical disinfectant/sterilant contact. Gowns must be changed between patient procedures or if visibly soiled.

(7) Protective apparel (i.e. gowns and masks) should not be worn outside the procedure room and cleaning room.

(8) All needles and sharps are to be appropriately disposed of in puncture resistant containers at their point of use. Do not recap needles.

(9) All personnel performing or assisting with endoscopic procedures and personnel responsible for reprocessing the equipment must be knowledgeable about the infectious and chemical hazards associated with these procedures and equipment, including the relevant Workplace Hazardous Material Information System guidelines (WHMIS).

2. Reprocessing of Endoscopes

Refer to the manufacturer's instructions for cleaning and disinfecting each specific model of endoscope. Trained personnel must perform this procedure.

(1) Inspection

(a) At all stages of handling, the endoscope should be inspected for damage.

(b) Leak testing of the endoscope, according to manufacturer's recommendations, should be performed each time prior to starting the cleaning process. A leak test involves applying air pressure to the inside of the endoscope insertion tube and watching for air bubbles, which identify leaks either in the covering or internally into one of the channels.

(c) If damage is detected during the leak test (i.e. bubbling occurs), do not proceed with cleaning. Send to the repair service immediately. If the scope cannot be cleaned prior to transport, ensure it is clearly labeed as "contaminated" and is packaged and transported appropriately.

(2) Cleaning

(a) Reprocess immediately after use. Do not allow to dry prior to manual cleaning. If unable to initiate the manual cleaning process immediately, the endoscope may be flushed and left soaking in an enzymatic detergent solution. It is important to remove all detachable parts before reprocessing.

(b) Meticulous manual cleaning is the most important step in the cleaning process.

(i) Wipe the outer surface of the endoscope with enzymatic detergent-soaked gauze immediately after removal from the patient. Using the air/water channel valve, flush the air/water channel with water from the water bottle. For endoscopes with an elevator wire, manual flushing of this channel with an enzymatic detergent and rinsing is required. Transport the scope to the cleaning area in a closed container.

(ii) After determining there are no leaks, fully immerse the scope in a solution of enzymatic detergent cleaner to prevent the drying of secretions. Brush all channels to remove organic material and decrease the number of organisms present. Ensure the air/water/CO_2 channels are also cleaned.

(iii) Ensure the outer surface of the scope is thoroughly cleaned. Use of a soft bristle toothbrush to clean the lens end is acceptable.

(iv) All channels must be irrigated and brushed to remove particulate matter. Channel irrigators should be used to facilitate cleaning of all channels. (However, a channel blockage can be missed by an all channel irrigator.)

(v) Rinse all the channels and the endoscope thoroughly with copious amounts of tap water (i.e. minimum 500 ml) following the cleaning process to remove the residual of the enzymatic detergent.

(vi) Remove all excess water from the channels by injecting air via the all-channel irrigator to decrease chances of diluting the disinfectant solution.

(vii) For endoscopes with an elevator wire, this channel must be manually flushed with an enzymatic detergent and rinsed.

(3) Sterilization and Disinfection

(a) Endoscopes that come in contact with mucous membrane (i.e., laryngoscopes, flexible endoscopes including bronchoscopes, colonoscopes, and duodenoscopes) require disinfection between uses.

(b) Non-Critical items (i.e. cameras, light source) require meticulous cleaning and low-level disinfection between use.

(c) Sterilization or high-level disinfection of the endoscope internally and externally must be performed after scrupulous mechanical cleaning has been completed. All processes may be rendered ineffective if any organic material or moisture is retained on or in the endoscope.

(4) Recommended Methods/Agents

(a) Chemical agents registered with Health Canada or the Federal Drug Administration (U.S. - FDA) as sterilant/disinfectants are appropriate for high-level disinfection.

(b) The manufacturer's instructions regarding use of disinfectant must be adhered to in order to ensure efficacy. Continuous use of a disinfectant solution for long periods eventually results in dilution and/or inactivation.

(c) Commercial test kits are available for chlorine, hydrogen peroxide, glutaraldehyde, and peracetic acid to determine whether an effective concentration of active ingredients is present despite repeated use and dilution. However, the reliability of such test kits has not yet been established.

(d) Ethylene Oxide (ETO) - Gas sterilization requires an extended time to complete the sterilization and aeration process so it may not always be practical.

(e) Steam sterilization - Cannot be used for flexible endoscopes but is the preferred method for rigid scopes.

(f) Glutaraldehyde preparations

(i) Alkaline Glutaraldehyde – ≥2% - Several preparations of glutaraldehyde are marketed as ≥2.4% solution to which a separately packaged "activating" preparation containing an alkaline buffer, a surface tension depressant, an anticorrosive compound and a water-soluble dye is added. The bicarbonate (buffer) raises the pH to 7.5 to 8.5, which greatly enhances the microbicidal (including sporicidal, fungicidal and viricidal) activity. Glutaraldehyde has excellent materials compatibility. In contrast to many disinfectants, it is highly resistant to neutralization by organic soil. Chemically stabilized solutions have a shelf life (i.e., a period during which they maintain adequate glutaraldehyde concentrations) of at least 14 days and of 28 days when in-use dilution does not exceed 50 per cent.

(ii) Acid Glutaraldehyde – ≥2% - Compared with alkaline preparations, some acid solutions are more corrosive to metal. Acid solutions of glutaraldehyde (pH 3.0 to 6.3) are stable for long periods without loss of active aldehyde groups. A ≥2% acid glutaraldehyde acts as a chemical sterilant and is acceptable for high-level disinfection.

(g) Hydrogen Peroxide (H_2O_2) - A 7.5% hydrogen peroxide/0.85% phosphoric acid solution is classified as a high-level disinfectant. Hydrogen peroxide is a rapid oxidizer, which facilitates removal of organic debris and is relatively free of toxic fumes. Although hydrogen peroxide is a potent antimicrobial agent, it can damage rubber and plastics, and corrodes copper, zinc, and brass. As with other

chemical sterilants, dilution must be monitored by regularly testing the minimum effective concentration (i.e. 6.0%).

(h) Peracetic Acid – 1% - A 1% peracetic acid solution has broad spectrum activity against bacteria, fungi, spores and enteroviruses. Although peracetic acid can be corrosive, an automated endoscope reprocessing system has been designed that dilutes 35% peracetic acid to a final concentration of 0.2% and adds a buffer and an anticorrosive agent. The system is designed only for reprocessing totally immersible endoscopes.

(i) Ortho-phthalaldehyde (OPA) - OPA has several potential advantages compared to glutaraldehyde. It has excellent stability over a wide pH range of 3-9 and is non-irritating to the eyes and nasal passages. Additionally, OPA requires no activation prior to use.

(5) Agents Not Recommended for Disinfection of Endoscopes

Some agents are not recommended for use on endoscopes and endoscopic equipment because of incomplete microbiologic coverage, toxic exposure to personnel or physical damaging to the equipment. These agents include:

(a) Products not cleared by Health Canada/ FDA for use on semi-critical or critical medical devices.
(b) Skin antiseptics (i.e. povidone - iodine, Chlorhexidine gluconate).
(c) Hypochlorite.
(d) Quaternary ammonium compounds.
(e) Phenolics.

(6) Rinsing

(a) To remove all traces of the disinfectant, adequate rinsing must follow the disinfection process. Any residual chemical can cause toxic effects in a patient if it is transmitted during the next endoscopic procedure. The use of sterile water for rinsing is preferred, but tap water can be used.

(7) Drying

(a) If tap water is used for the final rinse, always follow rinse step with 70% alcohol flush and dry with compressed air.
(b) Always use an alcohol flush and compressed air drying for scopes that will be stored before next use (i.e., not point-of-use reprocessing).
(c) Channel valves and video caps should be kept separately from scopes during storage to facilitate drying.
(d) Ensure the scope and channels are dried completely. Alcohol flush facilitates the drying.
(e) When a scope is processed through an AER, it still requires an alcohol rinse followed by manual forced air drying prior to storage.

(8) Storage

(a) Endoscopes should be stored hanging vertically in well-ventilated areas in a way that prevents recontamination or damage. They should not be coiled and stored in their cases.

(b) Store valves separately from endoscopes. Failure to do this may result in microbial overgrowth in the channels.

(c) Wipe down the storage cupboard weekly with an approved low-level disinfectant/cleaner.

(9) Automated Endoscope Reprocessors (AER)

(a) Endoscopy unit cleaning/disinfection processes may be standardized by the use of an automated endoscopic reprocessor. This equipment may be useful in circulating germicides, containing vapors, and decreasing exposure of personnel to contaminated equipment and disinfectants. Operation of this equipment should be limited to those individuals trained in its proper use.

(b) The use of any automated system must be preceded by meticulous manual cleaning and leakage check as previously described.

(c) The following capabilities must be present in any AER:

(i) Enzymatic detergents and/or disinfectants should be circulated through all channels at equal pressure without trapping air.

(ii) Washing and disinfecting cycles should be followed by thorough rinsing cycles followed by forced air to remove the used solution.

(iii) Disinfectant should not be diluted with wash or rinse water.

(d) Other considerations:

(i) If an alcohol rinse is not part of the AER cycle, perform alcohol rinse manually.

(ii) Forced air drying cycle or air drying by hand should be completed after the final rinse.

(iii) Routine disinfection of the AER according to the manufacturer's recommendations and institutional policy must be done.

(iv) When used to disinfect duodenoscopes, ensure the channel for the elevator wire is cleaned and disinfected as part of the processing cycle or it may require manual processing.

(v) Residual water remaining in the water hoses and reservoirs may cause microbial colonization of an AER. This could lead to contamination during subsequent instrument processing.

(vi) Protocols for both the specific scope and the specific AER (i.e., appropriate connecting systems) are necessary to ensure effective functioning of the AER.

(10) Special Considerations

Sterilization or high-level disinfection should be performed as directed by institutional policy. Diagnosed or suspected infection, including Hepatitis B, VRE, MRSA, HIV or *Clostridium difficile* is not a contraindication for endoscopy. It is not recommended to have instruments dedicated for use with infected patients.

3. Accessories

(1) It is recommended that all accessories be disposable.

(2) Non-disposable accessories require meticulous manual cleaning and disinfection or sterilization after each use according to manufacturer's guidelines and as directed by

institutional policy. Ultrasonic cleaning is more effective for cleaning stainless steel compared to plastic devices.

(3) Lubricate "O" rings on buttons, valves, and cleaning adaptors according to manufacturer's recommendations, as needed.

(4) Biopsy Forceps

(a) Meticulous manual cleaning with an enzymatic agent is required as soon as possible after the procedure.
(b) Ultrasonic cleaning is recommended to remove debris that hand cleaning can not. Biopsy forceps break the mucosal barrier; therefore, they are classified as critical items and require sterilization.
(c) The only method that will effectively penetrate the metal coils of the spring-like structure and any residual organic material is steam under pressure. Chemical sterilization does not completely penetrate the coils and therefore is not effective.

(5) Water Bottle

(a) For endoscopic irrigation, fill the bottle with sterile water.
(b) Sterilize or high-level disinfect the water bottle daily.
(c) Each endoscopic retrograde cholangiopancreatography (ERCP) procedure requires a fresh sterile bottle with sterile water.

(6) Other Accessories

(a) Accessories that penetrate mucosal barriers (i.e. papillotomes, cytology brushes) should either be disposable or mechanically cleaned utilizing an ultrasonic cleaner and sterilized between patient uses.
(b) Change the suction tubing between patients.

4. Medical Equipment

(1) There must be routine cleaning of non-critical equipment (i.e. teaching heads, light sources, cameras) using an approved low-level disinfectant/cleaner.

5. Environment

(1) General Cleaning

(a) For general cleaning of equipment such as procedure carts, stretchers, sinks, etc. after each use, use an approved low-level disinfectant/cleaner.

(2) Spills

(a) In keeping with routine practices:
(i) Using gloves, blot spills of blood or body fluid with disposable towels.
(ii) Wipe the area with clean, disposable towels soaked with an approved low- level disinfectant/cleaner. Disinfectant spills should be handled by consulting the solution MSDS (Material Safety Data Sheet) WHMIS Guidelines.

(3) Waste

(a) Minimal handling of all medical waste should be encouraged.
(b) The storage and disposal of waste should be handled according to institutional policy, city by-laws and provincial and federal guidelines.

(4) Facility Design

(a) Patient care areas should be separate from cleaning/disinfection areas.
(b) A designated area is required for hand washing.
(c) Clean and dirty areas should be separate with proper plumbing and drains. Ensure access to sinks to facilitate immersion of scopes during cleaning and rinsing.
(d) Adequate space should be provided for drying and storing endoscopes and endoscopic accessories.
(e) Air-exchange equipment (i.e. ventilation system, exhaust hoods, etc.) should be utilized to minimize the exposure to potentially toxic vapors. If glutaraldehyde is used for high-level disinfection, then periodic air quality monitoring for glutaraldehyde fumes should be performed and a log kept.

6. Continuous Quality Improvement

(1) Provide comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure they understand the importance of proper reprocessing. To achieve and maintain competency, each member of this staff should receive annually:

(a) Hands-on training with written endoscope specific processing instruction for every endoscope model and AER used at the facility. Work should be closely supervised until competency is documented for each reprocessing task from cleaning through storage of the endoscope.
(b) Additional training with documented competency for new models of endoscopes or AERs as they are introduced in the facility.
(c) Strict warnings with frequent reminders not to deviate from the written instructions for preparing endoscopes for patient contact.

(2) Implement a comprehensive quality control program. The reprocessing program should include:

(a) Visual inspections of the equipment to identify conditions that may affect the cleaning or disinfecting processes.
(b) Assurance that all manufacturer recommended maintenance schedules and services are performed for endoscopes and AERs used in the facility.
(c) Use of appropriate process monitors as recommended by the AER and germicide manufacturers.

(3) Records of the use of each endoscope, showing the patient upon whom it was used, the type of procedure involved, and the system used to reprocess the endoscope must be kept.

(4) A surveillance system capable of detecting clusters of infections or pseudo infections associated with endoscopic procedures must be in place.

(5) Although routine microbiologic sampling of inanimate environmental items is not recommended, microbiologic monitoring of flexible endoscope channels is the only direct method for assuring that the reprocessing procedures being used are reliable. If such monitoring is implemented as part of a quality assurance program, we recommend it be performed once every 4-6 months as a process validation test. An outline of the sample collection method and interpretative criteria are presented in Appendix One of Appendix F.

(6) Colonization of automatic endoscope reprocessors with opportunistic microorganisms may occur. Periodic culturing (no more frequently than quarterly) of an AER may thus be warranted.

(7) Culturing requires very precise techniques and should be done in close consultation with Infection Control and the microbiology laboratory.

J. Quality Assurance and Improvement

(1) Accreditation by The College of Physicians & Surgeons of Manitoba requires that quality assurance and improvement programs are in place. This process must include outcomes and recommendations.

(2) An internal process for regular chart audits must be in place .A summary of those findings must be included in the annual report by the Medical Director.

(3) Adverse event reports must be reviewed quarterly and a summary included in the annual report.

(4) Facilities must have a documented policy and procedure for addressing patient concerns/complaints.

K. Manuals

Policies and Procedures should reflect these and other published standards of the College and other recognized organizations. Their size and content will vary with the complexity and scope of the services offered by the facility.

The following are recommendations for full service non-hospital surgical facilities with several staff and physicians. Scaled down versions are recommended even for small NHMSFs.

1. Policy Manual

(1) Policy statements should be consistent with the goals of the organization.

(2) Policies should be developed for personnel, office, and procedures.

(3) The Medical Director or a designated person must ensure that all necessary policies are established, maintained, written, and implemented.

(4) All policies must be signed by the Medical Director or appropriate designate as developed.

(5) A process for review and signature by the Medical Director or appropriate designate must occur at least every 4 years.

(6) The policy manual must be available to all relevant staff. If there is more than one copy, then each must be numbered to ensure changes are made in identified manuals. One copy should be identified as the master copy.

(7) As changes are made, copies of past policies must be kept on file for legal purposes.

(8) Each policy should be complete within its identified numbered pages.

(9) The policy format should be consistent, standardized and easily identified as a policy.

(10) Header information on each policy should include (sample format - Appendix G):

- (a) Facility name.
- (b) Title of policy.
- (c) Original date of policy - which is carried forward on each review.
- (d) Revision dates - which should also be carried forward with changes.
- (e) The last revision date on each page.
- (f) The next expected revision/review dates (not more than 2 years).

(11) The contents of a Policy Manual should include, but is not limited to, the following:

- (a) Admission Criteria:
  - (i) Operating room
  - (ii) Post anesthesia Care Unit
- (b) Bomb Threat (for facilities where this may be a risk);
- (c) Critical Incident Management;

(i) Patients
(ii) Personnel
(iii) Equipment/Facility

(d) Death Notification, Management of
(e) Discharge Criteria:
(i) Operating Room
(ii) Recovery Room
(f) Documentation/Record Requirements:
(i) Health record/chart
(ii) Operating room nursing
(iii) Anesthesia provider
(iv) Surgeon
(v) PACU
(vi) Quality assurance
(vii) Statistics
(viii) Incidents/complications
(g) Emergency Patient Transfer
(h) Fire/Evacuation
(i) Infection Control
(j) Medical Record Management
(k) Monitoring Protocol
(i) Preoperative
(ii) Intraoperative
(iii) Postoperative
(l) Office Policies
(m) Organizational Chart
(n) Personnel:
(i) Content and access to personnel files
(ii) Occupational Health requirements
(iii) Orientation and education
(iv) Responsibilities
(v) Job descriptions
(vi) Employee rights
(o) Grounds for immediate dismissal.

2. Procedure Manual

(1) Current procedure manual(s) should be readily available in the appropriate work area.

(2) If the manual is separated into several work areas, one master manual should be maintained in a central location in the facility. Repetitive routines, such as cleaning protocols, should be summarized and posted on walls in actual work areas to assist with compliance.

(3) The Medical Director or a designated member of personnel should ensure that manuals are current and accurate.

(4) Each manual should contain a table of contents identifying a complete list of procedures and processes that are provided, as well as support processes, equipment requirements, and related routines in the facility.

(5) All physicians involved with the procedures should have knowledge of the written procedures and should be involved in changes to the procedures each provides.

(6) Related information should be consolidated in one section.

(7) All procedures must be signed by the Medical Director or appropriate designate as developed.

(8) A process for review and signature by the Medical Director or appropriate designate must occur at least every 4 years.

(9) The list of procedures must be those approved for the facility.

(10) A process to assess compliance with procedures should be in place.

(11) Vendor manuals should be attached to / located with or near each piece of equipment. Complex equipment should have quick reference summaries attached, e.g. electrosurgery and phacoemulsifier devices.

(12) All personnel must be orientated, upon hiring, to the procedure manuals. The extent of a step-by-step orientation of new personnel to each procedure will depend on the specific role of the new member, the risk of injury or damage and implications of non-compliance.

(13) Each member of the personnel should be responsible for updating or informing the appropriate person of a need to update procedures which they perform that may be inaccurate or outdated.

(14) A communication process should be established to inform the necessary personnel of changes in procedures, updates, and new procedures.

(15) Where significant changes to a procedure manual are made, the administrative area must keep a file of the previous procedure, for legal reasons.

(16) A standard format should be developed and used for all procedures. It should include, but is not limited to (sample format - Appendix H):

(a) Name of procedure
(b) Principle/purpose of procedure
(c) Patient preparation
(d) Equipment/supplies needed
(e) Equipment calibration steps and trouble shooting if applicable
(f) Special equipment cleaning/sterilizing
(g) Steps of procedure in sequential order
(h) Utilization of pictures and diagrams where helpful
(i) Rationale for steps in procedure included where helpful
(j) Limitations/potential complications
(k) Special safety precautions
(l) Normal result expected - age range and sex where applicable
(m) Clinical significance
(n) Critical values

(o) Reporting of results required
(p) Reference sources e.g. CSA documents, Provincial/National Standards, Vendor reference source
(q) Comments section for special notes
(r) Date procedure was established
(s) Last date of review/revision
(t) Source of approval (responsible person) - with actual signature

(17) The topics of Procedure Manuals should include, but are not limited to:

(a) Aseptic Practices:
  (i) Processing, handling, storage and control sterile goods
  (ii) Traffic restrictions
  (iii) Washing, storage, folding, reprocessing of fabrics for the operating room
  (iv) Packaging materials
(b) Infection Prevention:
  (i) Cleaning procedures - instruments, furniture, materials, devices
  (ii) Containment of soiled materials
  (iii) Hand washing
  (iv) Hand scrubbing protocols
  (v) Handling of infectious wastes (blood/body fluids)
  (vi) Handling of known infected/contagious patients
(c) Housekeeping (in the operating room) between cases, daily, weekly, and monthly;
  (i) Restriction of infected/contagious personnel
  (ii) Routine Practices
  (iii) Protective devices/equipment
  (iv) Soap/detergent/antiseptic use and dispensing (including approved agents)
  (v) Transport of soiled materials
(d) Management of Cardiopulmonary Arrest:
(e) Dress Code:
  (i) Identification of personnel
  (ii) Operating room dress code
  (iii) Dress code in non-operating room areas
  (iv) Protective clothing
(f) Emergency Patient Transfers – process to be followed
(g) Safety:
  (i) Handling and disposal of sharps
  (ii) Handling of waste products
  (iii) Process for personnel immunization
  (iv) Process for personnel injury at work
  (v) Process for management of needles/sharp injury with contaminated items
  (vi) Process for handling radioactive or dangerous/carcinogenic drugs/chemicals
(h) Equipment Sterilizers:
  (i) Operating instructions for each unit
  (ii) Process for record keeping for each load with parameters to be recorded
  (iii) Process for the use and recording of thermal, chemical and biological indications
  (iv) Process for frequency and method of cleaning units
  (v) Process for preventative maintenance

(vi) Process for breakdown and alternative operations

(i) Patient Care: (General and procedure specific)
- (i) Pre-facility visit requirements
- (ii) Admission criteria
- (iii) Pre-operative prep - by procedure/group of procedures
- (iv) Patient chart requirements

(j) Documentation details:
- (i) Supplies and equipment required
- (ii) Positioning procedures
- (iii) Skin preparation for surgery
- (iv) Draping procedures
- (v) Intra-operative care
- (vi) Post-operative care in theatre
- (vii) Management of complications
- (viii) Discharge teaching for each procedure/group procedure (patient and surgeon specific)

(k) Post Anesthesia Care Unit:
- (i) Admission criteria and care
- (ii) Documentation details
- (iii) Management of complications
- (iv) Discharge criteria
- (v) Call for ambulance/crisis details

(l) Work Station Duty Lists specific for each role, work area

3. Equipment Manuals

(1) Equipment Manual

(a) This manual should include, as a minimum, for each piece of equipment:
- (i) A list of contact personnel and phone numbers
- (ii) Manufacturer operating and troubleshooting instructions
- (iii) Preventative maintenance schedule and log
- (iv) Record of repairs

(2) Computer Manual

(a) This manual should include, as a minimum:
- (i) List of contact personnel and phone numbers
- (ii) Availability of software and back-up disks or tapes
- (iii) 3 Schedule for developing back-up discs or tapes
- (iv) Procedure to be used in case of computer failure
- (v) List of personnel who have access to information and software security codes
- (vi) Guidelines for protection of confidentiality of patient data
- (vii) Location of software source code listing and, where appropriate, details of signal acquisition and processing algorithms should be described

(3) Safety Manual

(a) This manual should include, as a minimum, the following sections:
- (i) General Safety

(ii) Medical Compressed Gases
(iii) Infection Control
(iv) Biohazardous Waste
(v) Electrical
(vi) Fire
(vii) Medical Emergencies

L. References

The College of Physicians & Surgeons of Manitoba would like to acknowledge The College of Physicians & Surgeons of Alberta for permitting the reproduction, in part, of their document "Non-Hospital Surgical Facility - Standards and Guidelines", March, 2009.

1. Guidelines to the Practice of Anesthesia, Canadian Anesthesiologists' Society, 2008
2. Independent Health Facilities: Clinical Practice Parameters and Facility Standards, CPSO, 2002
3. Hand Washing, Cleaning, Disinfection and Sterilization in Health Care, Health Canada, December 1998
4. The Canadian Committee on Antibiotic Resistance- Infection Prevention and Control Best Practices for Long Term Care, Home and Community Care including Health Care Offices and Ambulatory Clinics, 2007
5. Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for all Health Care Settings, Province of Alberta, January 16, 2008
6. Best Practices for Infection Prevention and Control Programs in Ontario, Ontario Ministry of Health and Long -Term Care, September 2008
7. Health Canada- Infection Control Guidelines- Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care, 1999
8. Health Canada- CCDR- Infection Control Guidelines; Prevention and Control of Occupational Infections in Health Care, 2002
9. WRHA- Infection Prevention and Control- Routine Practices – Self-Learning Package at www.wrha.mb.ca
10. Workplace Safety and Health Act and Regulations- Available at www.safemanitoba.com
11. Guidelines for Infection Prevention and Control in Endoscopy, Manitoba Advisory Committee on Infectious Diseases, September 2000
12. Manitoba Health, Manitoba Immunization Schedules- Reference Guide for Health Professionals, December 2008
13. WRHA – Tissue Bank Manitoba at www.wrha.mb.ca
14. Criteria for Accreditation of Ambulatory Surgical Facilities – Canadian Association for Accreditation of Ambulatory Surgery Facilities Inc.
15. WRHA Informed Consent Policy – July, 2007
16. Manitoba Building Code, Government of Manitoba
17. Safe Surgery Saves Lives (SSSL), Canadian Patient Safety Institute at www.patientsafetyinstitute.ca
18. Guidelines for the Design and Construction of Health Care Facilities – available at www.fgiguidelines.org

M. Appendices

1. Appendix A Pre-Survey Questionnaire
2. Appendix B CSA References
3. Appendix C Emergency Drugs
4. Appendix D Template of Annual Report to the College
5. Appendix E Template for Reportable Adverse Events
6. Appendix F Guidelines for Infection Prevention and Control in Endoscopy
7. Appendix G Sample Format for Policies
8. Appendix H Sample Format for Procedures