



Non-Hospital Surgical Facility General Standards

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1.0 Introduction

Alberta's *Health Professions Act* provides for the accreditation of medical services in non-hospital facilities by the College of Physicians & Surgeons of Alberta. Section 8.1 in Schedule 21 of the *Act* states:

8.1(1) A regulated member shall not provide a prescribed health service, or cause a prescribed health service to be provided, in a facility unless the facility is an accredited medical facility or a facility referred to in subsection (2).

(2) Subsection (1) does not apply with respect to a prescribed health service provided in

- (a) an approved hospital within the meaning of the *Hospitals Act*,
- (b) a hospital operated by the Government of Canada,
- (c) a health care facility operated by the Government of Canada or the Government of Alberta,
- (d) a hospital, clinic or centre operated by a regional health authority under the *Regional Health Authorities Act*,
- (e) a facility within the meaning of the *Mental Health Act* or an accredited health centre established for the purpose of section 49(b) of the *Mental Health Act*, or
- (f) a facility that is prescribed in the regulations.

Non-Hospital Surgical Facility services are one of many health services for which the CPSA requires accreditation. A complete list of prescribed health services is contained in the CPSA's by-laws and available on the CPSA's website.

The Advisory Committee on Non-Hospital Surgical Facilities is a standing committee of the College of Physicians & Surgeons of Alberta (hereinafter referred to as CPSA) which advises the Medical Facility Accreditation Committee (MFAC) of the CPSA with respect to all matters pertaining to non-hospital surgical facilities.

The Committee considers all issues related to the provision of surgical and anesthesia services with the facilities that may include but are not restricted to the following:

1. Develop and maintain evidence based standards and guidelines for anaesthetic and surgical care in NHSFs;
2. Inspect and audit the medical practices in NHSFs to ensure that medical services provide safe and effective patient care;
3. Provide advice to promote safe and effective practices in NHSFs;
4. Assess physicians' qualifications for privileges in NHSFs;
5. Inspect and audit of business practices in NHSFs to the extent necessary to ensure compliance with relevant CPSA by-laws.

The CPSA requires all accredited medical facilities to have a Medical Director (i.e. a practitioner who is registered with the Alberta College of Physicians & Surgeons) who is accountable for the practice of medicine within the facility. Medical Directors shall be satisfied as to the standing of other professionals (e.g. Dentists/OMFS, Nurses, Podiatrists) with their respective regulatory bodies and as to the safety of their practices.

NOTE: This document incorporates standards in a diagnostic and treatment facility approved by the Council:

- “shall” is used when a section is a requirement for accreditation;
- “should” is used when a section is recommended; and
- “may” is used when a section is discretionary.

2.0 Role of the CPSA

2.1 Accreditation of Facilities

- 2.1.1 All non-hospital diagnostic and treatment facilities, in which medical and surgical procedures are deemed by Council as having a sufficient risk of potential harm to a patient, shall register with and maintain accreditation by the College of Physicians & Surgeons of Alberta as a Non-Hospital Surgical Facility. In general, those procedures include:
1. Administration of general anesthesia, IV sedation requiring the monitoring of vital signs, or major regional blocks (See 3.0 Definitions); or
 2. Surgical or diagnostic procedures with risks of bleeding from major vessels, gas embolism, perforation of internal organs, or other life-threatening complications; or
 3. Surgical or diagnostic procedures requiring sterile precautions to prevent blood-borne, deep closed cavity, or implant-related infections.
- 2.1.2 Applications for accreditation of new facilities shall be made to the College of Physicians & Surgeons of Alberta.
- 2.1.3 The Standards of Practice as established by the Council of the CPSA are applicable. (The Standards define the practice of medicine and outline the responsibility of physicians for aspects of practice other than the direct care of patients.) The Medical Director's responsibilities include:
1. The qualifications and supervision of all staff who participate in patient care;
 2. The safety and quality of medical equipment used in the facility;
 3. The access to and confidentiality of medical records; and
 4. The propriety and accuracy of all claims for payment made by the facility for medical services provided in the facility but not for claims for payment made by individual members of the medical staff.
- 2.1.4 Accreditation involves:
1. Completion of a pre-assessment data verification form;
 2. An on-site assessment by one or more physicians (with expertise in the appropriate area of medical practice) designated by the CPSA;
 3. A review of all applications for privileges at the facility; and
 4. Review of the facility's compliance with the CPSA's standards.
- 2.1.5 In facilities owned and operated by a registered dentist/OMFS where the physician's only role is to administer anesthesia, accreditation relates to the practice of medicine and anesthesia only. The dentist/OMFS-owner is responsible for surgical standards and related administrative functions. The Medical Director shall be satisfied as to the safe and effective care of patients in the facility but may share the responsibilities listed (Section 4.1.2) with the dentist/OMFS-owner. Infection prevention and control standards applicable in these facilities are those established by the Alberta Dental Association and CPSA. This exception does not apply to physician-owned and operated facilities.

- 2.1.6 "Full Accreditation" is granted to those facilities with no identified deficiencies.
- 2.1.7 "Provisional Accreditation" may be granted for a 30 day period to those facilities with minor deficiencies to allow for their correction. A written response to each deficiency is required. A follow-up assessment may be required at the sole discretion of the CPSA. "Full Accreditation" will be granted when responses to deficiencies have been corrected to the satisfaction of the CPSA.
- 2.1.8 Requirements shall be met before accreditation will be granted or renewed by the CPSA.
- 2.1.9 The CPSA may revoke accreditation if practice in the facility is considered unsafe.
- 2.1.10 A "Certificate of Accreditation" will be issued by the College of Physicians & Surgeons of Alberta to all facilities with full accreditation.
- 2.1.11 Accreditation is limited to 4 years from the last date of approval unless extended by the CPSA and may be renewed through a process of reaccreditation which will follow the same steps as those for accreditation (refer to Section 2.1.4).
- 2.1.12 Payment to the CPSA for the cost of the assessment is the responsibility of the Medical Director of the facility.
- 2.1.13 "Spot" assessments conducted without prior notice may also be conducted. These are at no cost to the facility.

2.2 Administration

- 2.2.1 A record of each facility will be kept on file at the College of Physicians & Surgeons of Alberta.
- 2.2.2 The CPSA shall be advised of:
 - 1. Any change of ownership of the medical practice or Medical Director of the facility;
 - 2. Any major structural changes to patient care areas,
 - 3. Any major change in types of procedures or practices.
 - 4. Any significant increase in volumes of procedures performed (>50% of the previously recorded volume).
- 2.2.3 Each facility is required to pay an annual fee, set by Council, for the administration of the accreditation program.

3.0 Definitions

3.1 Anesthesia

- 3.1.1 General anesthesia is regarded as being a continuum of depressed central nervous system function from pharmacologic agents resulting in loss of consciousness, recall, and somatic and autonomic reflexes.
- 3.1.2 IV sedation is 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 IV sedation for credentialing or monitoring purposes. The provision of IV sedation includes, but is not limited to, the use of any IV agent for this purpose or of nitrous oxide in a greater than 50% concentration. 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 IV sedation.
- 3.1.3 Major regional blocks include, but are not limited to, brachial and lumbosacral plexus blocks, periorbital blocks, spinal and epidural blocks, and IV regional blocks. The risk of inadvertent CNS block of a higher level than intended mandates preparedness for support of vital functions.

3.2 Procedures

- 3.2.1 For the purpose of this document, "surgery" includes dental/OMFS procedures.
- 3.2.2 Procedures not permitted in physicians' offices or unapproved facilities are described in the CPSA's by-laws. Those procedures may be provided in accredited non-hospital surgical facilities with approval from the Advisory Committee advising on privileges in these facilities. The Committee will rely on expert opinion and available evidence in preparing its decisions.

4.0 Personnel

4.1 Medical Director

4.1.1 Qualifications

The Medical Director of each NHSF shall be a physician licensed to practice medicine in Alberta.

4.1.2 Duties

The Medical Director shall personally ensure the following:

1. The safe and effective care of patients in the facility;
2. That appropriate and up-to-date policy and procedures manuals are in place;
3. That the duties and responsibilities of all personnel are written and understood;
4. Ensure a policy is in place to provide safe care for patients requiring prolonged stay, beyond the regular hours of operation that includes a planning process that is documented and communicated to all team members.
5. That applications for privileges in anesthesia or surgery in the facility and changes to these privileges are approved by the appropriate College;
6. That sufficient numbers of appropriately trained personnel are present during procedures;
7. That procedures and equipment are appropriate and safe;
8. That arrangements are in place for the emergency transfer and admission of patients to hospital through agreements with admitting physicians to those hospitals;
9. That complete and accurate confidential patient records and documentation relating to the operation of the facility and procedures performed are kept;
10. That a quality assurance process shall in be place that identifies and monitors infection & medical complication rates involving the multiple health care professionals within the facility;
11. When complications are identified via the quality assurance process, the medical director will report such to the appropriate College(s); and
12. That documentation and fees required by the CPSA are submitted as required.

4.2 Physicians Requesting Privileges

4.2.1 Qualifications

1. All physicians who administer general anesthesia or major regional blocks in an NHSF shall:
 - a. Be registered in Alberta and be recognized as a specialist in anesthesia;

-and-

Maintain an active Regional (or hospital) medical staff appointment and active hospital anesthetic privileges **or** hold active certification in Advanced Cardiac Life Support (ACLS) as specified by the Heart and Stroke Foundation of Canada;

-or-

b. Be registered in Alberta and be approved by Council to administer anesthetics as a non-specialist;

-and-

Maintain an active hospital medical staff appointment and active hospital anesthetic privileges in the same community **and** hold current certification in Advanced Cardiac Life Support (ACLS) as specified by the Heart and Stroke Foundation of Canada;

-or-

c. in the case of retrobulbar blocks, be a physician registered in section (a) or (b) with training in this procedure approved by Council;

-or-

be registered in Alberta and be recognized as a specialist in ophthalmology with training in this procedure approved by Council.
2. All physicians who administer IV sedation in an NHSF shall:
 - a. Be qualified to administer general anesthesia in an NHSF and be registered in Alberta;

-or-

b. Have completed training in the administration and monitoring of IV sedation and provide an evaluation of his or her skills acceptable to the CPSA; and

- i. Hold active certification in Advanced Cardiac Life Support (ACLS)
 - or-
 - ii. Have immediate access to an on-site “code team” consisting of at least one physician and one registered nurse, each with active certification in Advanced Cardiac Life Support (ACLS)
3. All practitioners who perform surgery or dentistry under anesthesia, major regional block or IV sedation in an NHSF shall:
 - a. Be registered in Alberta as a physician, osteopath, dentist or podiatrist;
 - and -
 - b. Have successfully completed supervised training and provide an evaluation of his or her skills in the particular (or substantially similar) procedure performed in accordance with standards of training and performance acceptable to their Council;
4. All practitioners with any of the above privileges shall maintain competence through appropriate continuing education and should be observed periodically and evaluated (formally or informally) by peers who perform the same procedures; and
5. All practitioners with any of the above privileges should participate in mock drills for the management of life-threatening emergencies related to the procedures each performs.

4.2.2 Application

1. A physician or osteopath seeking privileges in anesthesia* or surgery** in an NHSF approved by Council shall apply in writing to the Medical Director of the facility.

*NOTE: *Anesthesiologists with privileges in a Regional Health Authority need only apply once to the CPSA for approval to provide services in NHSFs in Alberta. Medical Directors must request confirmation of this approval from the CPSA prior to services being provided in their facility.*

***Only those surgical procedures approved by Council will be considered for approval. (Refer to Approved Procedures for Non-Hospital Surgical Facilities at www.cpsa.ca.)*

2. Any application by a physician seeking privileges who DOES NOT hold those privileges in facilities administered by a Regional Health Authority shall include, at a minimum:
 - a. the physician's name, address, and registration number with the CPSA;
 - b. details of the same or similar privileges, if any, currently held in other facilities;
 - c. numbers of procedures performed during the past year similar to those for which he/she is seeking privileges and the name(s) of the facilities in which they were performed;
 - d. any other relevant past experience; and
 - e. letters from two physicians attesting to the skill and judgment of the applicant to perform such procedures.

3. Any application by a physician seeking privileges who DOES hold these privileges in facilities administered by a Regional Health Authority shall include:
 - a. the physician's name, address, and registration number with the CPSA;
 - b. description of the privileges currently held in a Regional facility; and
 - c. letter from the Regional Health Authority confirming the privileges held and the good standing of the applicant.

4. In the case of urgently required privileges the Medical Director may grant temporary privileges for no greater than 5 working days when he/she has sufficient knowledge of the competence of the applicant in the procedures requested and the good standing of the applicant with their College. The Medical Director shall notify the appropriate College of any such privileges in writing within one week.

5. The Medical Director shall forward a copy of all applications for privileges, including those of the Medical Director, to the CPSA together with his/her assessment of the suitability of the applicant and the privileges requested.

NOTE: Applications for privileges for the Medical Director must include two letters of reference attesting to competence for the procedures requested.

6. Except as described in section (4.2.2.4) above, no privileges may be granted by the Medical Director until approved by the appropriate College.

7. The Advisory Committee designated by the Council shall consider all applications and make recommendations as to privileges.

8. Interim recommendations may be made by the Registrar, to be amended or confirmed at the next meeting of the Advisory Committee designated by Council.

9. The decision of the Advisory Committee will be sent to the physician applying for privileges and to the Medical Director.

10. Appeals of the Committee's decision shall be made in the first instance to the Registrar, who may refer it back to the Committee for reconsideration.
11. A further appeal may be made to Council if necessary.
12. It may be considered unbecoming conduct for a medical practitioner to perform any procedure in a Non-Hospital Surgical Facility for which privileges have not been recommended by the CPSA.
13. The Medical Director shall maintain an up-to-date list of all privileges approved for each physician in the facility and a file with all applications and reapplications for privileges for assessment by the CPSA upon request.
14. Applications for additional privileges of a different type than currently held in the facility by the physician shall be sent by the Medical Director to the CPSA for review by its Advisory Committee.

4.2.3 Annual Facility Renewal of Privileges

1. On an annual basis, physicians shall provide to the Medical Director a copy of the regional health authorities' confirmation of privilege renewal in the region.
2. Physicians that do not hold regional privileges shall make re-application to the Medical Director annually and include:
 - a. The approximate number of each surgical or medical procedure or the totals of general anesthetics, IV sedations, and/or major regional blocks performed during the previous year;
 - b. Any changes to privileges in this or other health care facilities during the previous year;
 - c. A summary of CME and any performance reviews undertaken during the previous year;
 - d. The outcome of discipline for professional conduct or competence during the previous year by any professional body; and
 - e. Any other matters which may affect a physician's competence or performance
3. The Medical Director shall also keep on file confirmation of renewal of regional health authority privileges; or, as in 4.2.3.2 if regional privileges are not held.
4. The Medical Director shall advise the appropriate College or regulatory body of any information contained in a re-application for privileges which, in his/her opinion, could adversely affect a decision to continue privileges.

5.0 Patient Care

5.1 Pre-Operative Evaluation

5.1.1 Patient Selection

All patients undergoing anesthesia (as defined in Section 3.1.) in an NHSF shall be assigned an American Society of Anesthetists (ASA) classification of physical status by an anesthesiologist. Class III and IV patients may be accepted only if the patient's disease entity could not reasonably be expected to be affected adversely by the anesthetic or the procedure. A discussion shall occur between the surgeon and anesthesiologist, well in advance of the scheduled procedure, for all Class III and IV cases, and for any patient with a BMI > 35. The discussion will focus on the appropriateness of the NHSF setting, the pre-operative evaluation and care, and the intra-operative and post-operative requirements for safe performance of the procedure. This shall be documented on the patient's record.

ASA Physical Status Classification

ASA I	A normal healthy patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease limiting activity but NOT INCAPACITATING
ASA IV	A patient with INCAPACITATING systemic disease that is a constant threat to life
ASA V	A moribund patient not expected to live 24 hours with or without operation

5.1.2 Patient Assessment & Care

1. A history and physical examination shall be performed within 90 days of the procedure by a registered physician, oral surgeon, podiatrist, osteopath or nurse practitioner. This shall be updated if necessary within 2 weeks of the procedure, documented, dated and signed, and be part of the patient's clinical record pre-operatively.
2. Each patient who is to undergo a major regional or a general anesthetic or who is to be sedated and monitored by an anesthesiologist, shall have a documented, dated and signed, pre-operative anesthetic assessment not more than 2 weeks before the anesthetic.
3. The pre-anesthetic assessment should be carried out by the anesthesiologist who is to provide the anesthetic services.

4. The pre-anesthetic assessment shall include:
 - a. A review of the patient's clinical record;
 - b. A medical interview with the patient;
 - c. A physical examination relative to anesthetic aspects of care;
 - d. A review and ordering of tests as indicated;
 - e. A review or request for medical consultations as necessary for patient assessment and planning of peri-operative care; and
 - f. Orders for pre-operative preparation such as fasting, medication, or other instructions as indicated.

5. The patient or responsible adult shall be given adequate opportunity to provide information, to ask questions and to have a satisfactory explanation of the procedure and of the proposed choice of anesthetic by the physician(s) responsible for each.

5.1.3 Surgical Safety Checklist

1. A Surgical Safety Checklist shall be completed by all members of the surgical team to communicate safety checks at three critical points:
 - a. Briefing – before induction of anesthesia
 - b. Time out – before skin incision
 - c. Debriefing – before patient leaves the OR

2. Completion of the Checklist shall be documented.

3. There shall be a policy and procedure for the use of the Surgical Safety Checklist.

5.1.4 Patient/Site/Side Identification

1. There shall be a process, with a written policy and procedure, to verify the identity of the patient and the correct surgical site and side.

2. This shall be documented and include:
 - a. A detailed pre-operative identification/verification process; (information gathering, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the pre-operative preparation of the patient, up to and including the "time out" just before the start of the procedure)

 - b. Marking the operative site; (for procedures involving right/left distinction, multiple structures such as fingers and toes, or multiple levels as in spinal procedures, the intended site must be marked such that the mark will be visible after the patient has been prepped and draped).

- c. "Time out" immediately before starting the procedure; (active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode whereby the procedure is not started until any questions or concerns are resolved).

5.1.5 Signed Informed Consent

1. The patient or legal guardian shall give signed informed consent for the procedure/anesthetic and this shall be part of the patient's clinical record.

5.1.6 Facilities performing surgical procedures where the need for blood replacement might reasonably be anticipated shall have policies and procedures for:

1. preoperative group-and-screen; or
2. crossmatching of blood; and
3. the availability of blood in response to an emergency request. It is recommended that blood be available on-site within 30 minutes.

5.1.7 Facilities performing the surgical procedures referred to in section 5.1.6 and which do not store crossmatched blood on-site should maintain a supply of a colloidal volume expander for emergency use.

5.2 Intra-Operative Management: Anesthesia & IV Sedation

This section deals with the requirements for managing patients undergoing both general and regional anesthesia and for sedated patients where awareness and protective reflexes may be obtunded.

5.2.1 General anesthesia and major regional blocks shall be administered by a qualified physician with privileges in these procedures. The anesthesiologist shall remain with the patient at all times throughout the conduct of the anesthetic until the patient is transferred to the recovery area.

5.2.2 IV sedation shall only be administered by or under the direct supervision of a physician approved by the CPSA or a dentist or oral surgeon approved by the Alberta Dental Association & College to provide IV sedation. In the absence of an anesthesiologist, the patient shall also be attended by a second individual (a registered nurse, physician, or dentist) who is not assisting in the surgical procedure and who is trained to monitor patients under IV sedation.

5.2.3 It is the responsibility of the surgeon to ensure that the second individual in 5.2.3 is adequately trained to perform his/her duties. Recognizing there is no formal training for this position, the surgeon shall ensure the assistant possesses the skills described below:

1. Assessing and maintaining a patient airway;
2. Monitoring vital signs;
3. Venipuncture;
4. Recording appropriate records;
5. Administering medications as required;

6. Assisting in emergency procedures including the use of a bag-valve-mask device; and
 7. Current ACLS certification is recommended.
- 5.2.4 Patients undergoing a general anesthetic or major regional block shall be continuously evaluated with at least the following:
1. Visualization of some portion of the patient under appropriate lighting;
 2. Pulse oximeter with audible signal recognition;
 3. End tidal carbon dioxide monitoring for each intubated patient, including endotracheal tube or laryngeal mask;
 4. Apparatus to measure blood pressure with an appropriately sized cuff;
 5. ECG with audible signal recognition;
 6. Peripheral nerve stimulator whenever muscle relaxants are used; and
 7. Agent-specific gas monitor, whenever inhalation anesthetic agents are used.
- 5.2.5 Patients undergoing IV sedation shall be continuously evaluated with at least the following:
1. Visualization of patient airway under appropriate lighting;
 2. Pulse oximeter with audible signal recognition; and
 3. Apparatus to measure blood pressure with an appropriately sized cuff.
- 5.2.6 In addition to items listed above in 5.2.5 and 5.2.6, devices or drugs which shall be immediately available include:
1. A stethoscope.
 2. A source of oxygen.
 3. A means of delivering positive pressure oxygen such as a self-inflating bag-valve-mask device.
 4. An emergency resuscitation cart which includes:
 - a. A cardiac monitor;
 - b. A manual defibrillator or an automatic or a semi-automatic external defibrillator (AED/SAED);
 - c. Apparatus to measure temperature;
 - d. Facilities providing **IV sedation only may** have an automatic or a semi-automatic external defibrillator (AED/SAED) only and are not required to have a cardiac monitor.
 [AED/SAED models must be compliant with current requirements of the American Heart Association and be approved for pediatric use if providing care for patients <8yrs old]
 - e. Endotracheal tubes, laryngeal masks, stylets, airways and facemasks in a selection of sizes appropriate to the expected range of patient sizes and ages; two functioning laryngoscopes and a variety of sizes of laryngoscope blades;
 - f. Magill forceps;

- g. IV supplies and accessory equipment such as syringes, needles, ECG leads, sponges, tape, etc. These shall be stored in an orderly manner and be easily accessible;
- h. Cricothyrotomy kit;
- i. A backboard for CPR if the surgical chair/table or recovery stretcher are not suitable; and
- j. Drugs as listed in Appendix A.

5.2.7 Patients undergoing retrobulbar anesthesia shall be continuously evaluated with at least the following:

- 1. Visualization of some portion of the patient under appropriate lighting;
- 2. Pulse oximetry; and
- 3. Apparatus to measure blood pressure.

5.2.8 In addition to items listed in 5.2.8, devices which shall be immediately available include:

- 1. A stethoscope;
- 2. A source of oxygen;
- 3. Oropharyngeal airways;
- 4. A means of delivering positive pressure oxygen such as a self-inflating bag-valve-mask device; and
- 5. A cardiac monitor with defibrillator or an automatic or a semi-automatic external defibrillator (AED/SAED). AED/SAED models must be compliant with current requirements of the American Heart Association.

5.3 Intra-Operative Management: Surgical

5.3.1 The surgeon, in collaboration with scrub personnel, is responsible for the maintenance of sterile conditions in the operating field, for the conduct of surgical procedure, and for the post-operative care of the operative site. The surgeon is also responsible for the post-operative care of the patient after discharge from the recovery room.

5.3.2 Except as specifically excluded by written policy, all tissues removed shall be sent for pathologic examination. There shall be a process to document the tracking of tissues and other specimens sent for pathologic examination that would include:

- 1. identity of the specimen sent,
- 2. patient name and a second identifier,
- 3. name of the person releasing the specimen and date and time,
- 4. name of the person/service transporting the specimen and date and time

5.3.3 The surgeon shall ensure the safe use of all surgical equipment and ensure all operating room personnel have been instructed in safety precautions specific to each (e.g., electrocautery, lasers, etc.).

5.4 Recovery Room Management

- 5.4.1 A recovery room, which may be the operating room if not required for another case, shall be available for the patient's safe emergence from anesthesia.
- 5.4.2 Requirements for post-operative care and monitoring following **general anesthesia/IV sedation** during the post-anesthetic recovery period include:
1. An anesthesiologist shall remain continuously available while the patient is intubated and be in attendance for extubation.
 2. After general anesthesia, an anesthesiologist shall accompany the patient to the recovery room, communicate the appropriate information, and provide written orders for the attending nursing personnel.
 3. Until such time as a patient meets documented criteria for discharge from the recovery room after general anesthesia or IV sedation: an anesthesiologist or a registered nurse trained in patient assessment and recovery room procedures shall remain in continuous attendance of the patient. A registered nurse who is responsible for these duties shall possess the skills described below:
 - a. Maintaining a patent airway;
 - b. Monitoring vital signs;
 - c. Venipuncture;
 - d. Recording appropriate records;
 - e. Administering medications as required;
 - f. Assisting in emergency procedures, including the use of a bag-valve-mask device;
 - g. Current ACLS certification; and
 - h. Current PALS certification if care is provided to patients less than or equal to 8 years of age.
 4. Ongoing assessment of each patient shall include an evaluation of heart rate, blood pressure, oxygen saturation by pulse oximetry (recommended also during recovery from uncomplicated regional anesthesia), color, level of consciousness, respiration and activity.
 5. ECG monitoring shall be immediately available for use on patients in the recovery room.
 6. Suction, oxygen and a bag-valve-mask device shall be immediately available.
 7. Adequate intravenous and other medical/surgical supplies, and medication required for patient care post-operatively shall be immediately available.

8. Patients who are resuscitated after a cardiac arrest shall be transferred to hospital by emergency medical services accompanied by the attending anesthesiologist as soon as safely possible but always within one hour of return of circulation.

5.5 Discharging the Patient

- 5.5.1 The anesthesiologist or other physician qualified to administer IV sedation or anesthesia shall remain on the premises of the NHSF until the patient meets documented pre-determined recovery criteria using a validated grading system (e.g. Analgesia and Anesthesia..., Current Researches, Volume 49(6): 924-934, Nov-Dec 1970. "A Postanesthetic Recovery Score" by J.A. Aldrete and D. Kroulik.).
- 5.5.2 The anesthesiologist is responsible for writing the discharge order. However, the actual decision for discharge from the recovery room, based upon established written criteria, may be delegated to trained recovery room personnel.
- 5.5.3 All patients shall be advised of the necessity to be accompanied from the facility by a responsible adult.
- 5.5.4 For patients who are unable or unwilling to arrange to be accompanied by a responsible adult, the following additional measures shall be undertaken:
 1. The attending physician shall document in the patient's chart that:
 - a. the patient was advised of the importance of an accompanying adult at the time of discharge,
 - b. the attending physician agrees that it is in the patient's best interests to proceed with the surgery in spite of the absence of an accompanying adult.
 2. The attending physician should obtain the patient's signature confirming their understanding of the risks.
 3. The patient shall remain in the facility until the attending physician determines that the patient's cognitive and physical parameters exceed facility criteria and that the patient can function independently. If the patient does not meet these criteria, then the attending physician shall make arrangements for ongoing care.
 4. A discharge order shall be written by the attending physician that includes documentation of: patient cognition, vital signs and readiness for discharge without a responsible adult.
 5. The method of transportation reported by the patient shall be documented as acceptable to the attending physician
- 5.5.5 Appropriate verbal and written post-discharge instructions shall be given to the patient and an accompanying adult.

- 5.5.6 Instructions not to drive or operate hazardous equipment for 24 hours after a general anesthetic, a major regional block or IV sedation shall be given to the patient and accompanying adult.
- 5.5.7 Instructions shall be given to the patient and an accompanying adult explaining the procedure for accessing emergency care if necessary.
- 5.5.8 Instructions shall be given to the patient and an accompanying adult informing them that the facility should be notified in the event of any unexpected admission to a hospital within 10 days of treatment at the facility.

6.0 Infection Prevention and Control

These standards have been adapted from Provincial Infectious Diseases Advisory Committee - Best Practices for Cleaning, Disinfection and Sterilization in all Health Care Settings; 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 Clinic, and Health Canada – Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care and Health Canada – Infection Control Guidelines – Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care.

Routine infection control practices shall be incorporated into everyday patient care. Institutional policy shall provide for education of every care provider in the principles of routine precautions, provision of adequate equipment to implement them, and a means by which compliance with practice can be monitored and audited.

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.

The institution/facility is responsible for ensuring that appropriate precautions are taken for specific patients.

All personnel (physicians, nurses, technologists/technicians, students, volunteers and others) are responsible for complying with routine 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.

All efforts should be made to prevent the transmission and acquisition of infections at the facility. The NHSF is expected to have well designed facilities, well documented policies and procedures, properly trained personnel, and an orderly pattern of work flow, all of which contribute to an improved standard of care and a lower risk of nosocomial infections.

6.1 Occupational Health/Immunization

The *Occupational Health and Safety Act, Regulation and Code* will also apply. Copies of the OHS Act, Regulation and Code, and "*A Physician's Guide to Occupational Health and Safety Responsibilities*" are available on-line at www.worksafely.org.

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

6.1.2 Immunization should be offered if immune status is unknown.

6.1.3 Immunization standards for medical office workers include:

1. Hepatitis B vaccine - highly recommended for all personnel at risk of potentially harmful contact with blood and body fluids.
2. Influenza vaccine - recommended for all personnel.
3. Measles (Rubella) vaccine - highly recommended for personnel who do not have a documented history or laboratory evidence of immunity. If this is lacking for any one of measles, mumps, or rubella, it is recommended that MMR vaccine be given.
4. Rubella vaccine - required by law in Alberta for all personnel who may have face to face contact with patients and do not have a documented history of receiving rubella vaccine or a laboratory result indicating immunity.
5. Tetanus & Diphtheria toxoids - recommended at 10-year intervals.
6. Tuberculin Skin Testing - recommended for all personnel at the beginning of their employment.

6.1.4 All personnel shall understand and adhere to "Routine Practices" which incorporate universal blood and body fluid precautions such as described in the "Health Canada Infection Control Guideline: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care, 1999" (This guidelines is available online at <http://www.hc-sc.gc.ca/hpb/lcdc>). Those precautions include:

1. The proper use of personal protective devices such as gowns, gloves, visors, and masks.
2. The proper use, storage and disposal of sharp devices and biological waste.
3. An approved method for the storage and disposal of blood and body fluid spills.
4. 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.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/98pdf/cdr24s8e.pdf>).
5. Appropriate containment of soiled items.

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

6.1.6 Consultation with a specialist in infectious disease shall be obtained prior to workers with blood-borne 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, CDR 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>).

6.1.7 Sharps shall be disposed in clearly labeled puncture resistant containers, and transported and disposed of according to the local regulations.

6.1.8 Sharps containers shall not be over-filled, and one container shall never be emptied into another.

6.1.9 Food and beverages consumed in personnel lounges shall be disposed of or stored away daily, and the area cleaned to prevent rodent and insect infestations.

6.2 General Infection Prevention Measures

6.2.1 Personnel shall be familiar with and adhere to aseptic techniques. Training in aseptic technique by a qualified person shall be offered to all new employees involved in direct patient care.

6.2.2 There shall be at least one sink for hand scrubbing and hand washing that shall not be used for any other purpose, which is of sufficient depth to prevent back splashing onto the hands, and which can be operated without the use of hands.

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

6.2.4 All personnel who scrub for procedures shall follow an approved hand scrub protocol prior to each operating procedure. Anesthesiologists and all circulating personnel shall hand wash with an antiseptic 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*.)

6.2.5 An antiseptic preparation should be used for all surgical scrubs and whenever aseptic technique is used. Sterile towels shall be used to dry hands prior to a procedure or donning sterile gloves.

6.2.6 Containers of soaps, antiseptics, and other solutions shall not be topped up. If containers need to be re-used, they shall be emptied, properly cleaned, and dried before re-use. A cartridge system that cannot be topped up is preferred.

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

6.2.8 The use of multi-dose vials is strongly discouraged. If they are used, care shall be taken to not contaminate the contents of the vial. The rubber diaphragm shall be wiped with alcohol, and a clean needle and clean syringe shall be used **each** time the vial is entered. The date the vial is first used shall be recorded on the vial. The opened vial should be discarded within a period recommended by the manufacturer or within one month if longer storage (than the manufacturer's recommendation) can be shown to be safe.

6.2.9 Drugs shall never be delivered from a common IV bag, IV tubing or syringe to more than one patient.

6.2.10 Air flow and quality in operating suites shall be monitored and maintained according to standards applicable for the type of surgical procedures performed.

NOTE: Consideration shall 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, non-implant, minor surgery procedures, the air exchanges could be in the 12-15 range per hour. The facility shall have on record, a dated engineering report that states the actual air exchange for the purpose of the current accreditation and infection control safety. Following are referenced recommendations:

	Minimum Air Exchanges Per Hour	Reference
Operating Room	15	"American Society of Heating, Refrigeration, and Air-conditioning Engineers, Inc (ASHRAE Handbook) (all outdoor systems)
	15	"Technical Design Guidelines for Health Care Facilities" (The "Blue Book") – Alberta Infrastructure and Transportation
	20	"CAN/CSA – Z317.2-M91 Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities"
Emergency and other treatment areas	12	

Note: *The Centers for Disease Control and Prevention Guideline for Prevention of Surgical Site Infection*, 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.

- 6.2.11 Adequate hand washing sinks shall 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.
- 6.2.12 Hand hygiene (washing with soap and water or using alcohol-based hand rub [ABHR]) shall be performed before contact with a patient or the patient's environment, before a clean or aseptic procedure, after exposure to blood, body fluids or touching contaminated items, following removal of gloves and after contact with a patient or patient's environment. Hands should be washed with soap and water if they are visibly soiled..
- 6.2.13 Alcohol-based hand rub (ABHR) products and/or hand hygiene sinks shall be available at the point of care.
- ABHR products shall contain 60-90% alcohol;
 - Hand hygiene sinks shall be used only for the purpose of hand hygiene and not used for equipment cleaning, waste disposal or food preparation;
 - Single use towels shall be available and used to dry hands following hand washing.

- 6.2.14 Masks and eye protection or full face shields shall 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.
- 6.2.15 Clean non-sterile gloves shall be worn:
- for contact with blood, body fluids, secretions and excretions, mucous membranes, draining wounds or non-intact skin (open skin lesions or exudative rash);
 - when handling items visibly soiled with blood, body fluids, secretions or excretions;
 - when the healthcare worker has open lesions on the hands.
- 6.2.16 Gloves are to be removed and hand hygiene performed washed immediately after completion of care or procedure; at point of use and before touching clean environment surfaces.
- 6.2.17 There shall be a designated person responsible for the maintenance and enforcement of infection prevention and control and occupational health & safety standards in the facility.
- 6.2.18 Traffic in patient care areas and particularly in operating room suites should be restricted to authorized personnel.
- 6.2.19 Doors to the operating room suites shall be kept closed, except for entry and exit by operating room personnel, especially during procedures.
- 6.2.20 Personnel shall not eat or drink in any area where direct patient care is provided or where reprocessing occurs.
- 6.2.21 A new virus filter shall be placed at the patient end of the circuit or a clean anesthetic circuit shall be used for each patient.
- 6.2.22 Linen, bed and pillow covers shall be changed between patients. Beds and stretchers shall be wiped down between patients.
- 6.2.23 Patient care items such as K-basins, thermometers, etc., shall not be used between patients unless reprocessed according to the manufacturer's guidelines. Other items, such as cups, should be disposable.
- 6.2.24 Drinking water for personnel and patient use shall be obtained from a clean sink or dispensing apparatus.
- 6.2.25 Medications that require refrigeration shall not be stored in a common fridge with food or beverages.
- 6.2.26 No animals other than seeing-eye dogs should be allowed in the facility.
- 6.2.27 If an aquarium is kept, it should be kept away from patient care areas. A cleaning protocol shall be established which contains safeguards against environmental contamination of the facility.

6.2.28 The facility shall 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.

6.3 Additional Precautions

6.3.1. Airborne Transmission Precautions

- a. Patients with known or suspected infectious tuberculosis, measles, varicella or disseminated zoster should be placed directly in a single examination room and the door shall remain closed.
- b. Those patients shall wear a surgical/procedure mask during transport and movement through the facility.
- c. High efficiency dust/mist masks shall be worn by all healthcare workers who enter the examination room of a patient with infectious tuberculosis.
- d. High efficiency dust/mist masks shall be worn by non-immune healthcare workers who absolutely must enter the examination room of a patient with varicella, disseminated zoster or measles.

6.3.2. Droplet Transmission Precautions

- a. Patients with known or suspected meningococcal infection, rubella, mumps, pertussis, diphtheria, or hemorrhagic fevers should be placed in a single examination room. If this is not possible the patient shall maintain a one meter spatial separation between 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 shall wear a surgical/procedure mask during transport and movement through the facility.

6.3.3. Contact Transmission Precautions

- a. Patients with known or suspected diarrhea, extensive skin or wound infection not contained by dressings, hemorrhagic fevers, meningitis, hepatitis, herpes simplex-disseminated, scabies (extensive or Norwegian/crusted), varicella, disseminated or extensive uncovered zoster and Antibiotic Resistant Organisms (ARO) should be placed in a single examination room. If this is not possible, a spatial separation of one meter shall be maintained between patients.
- b. Gloves should be worn when entering the patient's room or designated examination space.

- c. Gloves shall be removed before leaving the patient's room or designated examination space.
- d. Hands shall be washed immediately, first with soap and water if visibly soiled, then an antiseptic agent.
- e. Equipment and surfaces in direct contact with the patient or infective materials shall be cleaned before the room is used by another patient.

6.4 Patient Care Practices

- 6.4.1 There shall be a mechanism to catalog all adverse events including, but not limited to: breaks in sterile technique, significant exposures to blood and body fluids, needlestick injuries, inadvertent use of improperly sterilized equipment, and related breaches of policy and deviations from standard procedure.
- 6.4.2 There shall be a mechanism of surveillance and review of post-operative infection rates, and a record of consultations undertaken as a result.
- 6.4.3 The prevention of nosocomial infection should be a continuing education subject for all personnel.
- 6.4.4 The Medical Director is ultimately responsible to correct any deficiencies and to seek expert advice when needed.

6.5 Reprocessing (Cleaning, Disinfection, and Sterilization)

6.5.1 General

- 6.5.1.1 There shall be no re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.
- 6.5.1.2 All critical medical equipment shall be sterilized before each patient use. (medical equipment that enters sterile tissues, including the vascular system)
- 6.5.1.3 All semi-critical medical equipment shall receive a minimum of high level disinfection before each patient use. (medical equipment that comes in contact with non-intact skin or mucous membranes)
- 6.5.1.4 There shall be current written policies and procedures on all steps of reprocessing readily available for staff.
- 6.5.1.5 There shall be written information from the manufacturer on the safe and appropriate reprocessing of this medical equipment, included in the written procedures.
- 6.5.1.6 There shall be a designated reprocessing area that is separate from patient care areas.

- 6.5.1.7 Hand hygiene stations for staff shall be readily available in the reprocessing area. (Either hand washing sinks or alcohol dispensers.)
- 6.5.1.8 Clean Personal Protective Equipment (PPE) shall be worn by staff when reprocessing. (Eye protection or face shields, masks, gowns, gloves.)
- 6.5.1.9 There shall be a designated staff member responsible for reprocessing.
- 6.5.1.10 There shall be documented training process for staff performing reprocessing.

6.5.2 Cleaning

- 6.5.2.1 Cleaning detergent and solutions shall be used according to the manufacturer's written instructions.
- 6.5.2.2 Cleaning with detergent or enzymatic solutions and clean water shall always precede subsequent high-level disinfection or sterilization processes.
- 6.5.2.3 Cleaning shall always be performed as soon as possible after use to prevent bio-burden from hardening.
- 6.5.2.4 Instruments may be immersed in an appropriate solution if cleaning will be delayed.
- 6.5.2.5 Detergent or enzymatic cleaning solutions shall be discarded after each use.
- 6.5.2.6 Manual cleaning using friction shall be performed using cleaning accessories (brushes or sponges.)
- 6.5.2.7 Cleaning accessories shall be disposable or thoroughly cleaned and shall be high level disinfected or sterilized between uses.
- 6.5.2.8 If mechanical cleaning is performed with automated washer-decontaminators/disinfectors, pre-cleaning shall be performed manually.
- 6.5.2.9 If ultrasonic washers are used, equipment shall be thoroughly rinsed with clean water prior to additional reprocessing steps.
- 6.5.2.10 Automatic washers and ultrasonic cleaners shall be used in accordance with the manufacturer's written instruction.
- 6.5.2.11 There shall be documented preventative maintenance of the automatic washer as specified by the manufacturer.

- 6.5.2.12 Cleaning protocol/procedure shall include the following steps prior to high level disinfection or sterilization:
- disassembly (if applicable);
 - sorting and soaking;
 - physical removal of organic material;
 - rinsing;
 - drying;
 - physical assessment;
 - wrapping (if applicable)
- 6.5.2.13 There shall be a designated area for soiled supplies. This area shall be physically separated from patient care areas and from areas housing clean and sterile supplies.
- 6.5.2.14 The soiled area should have:
- Adequate counter space to receive soiled supplies.
 - A double utility sink to rinse and clean soiled items.
 - A flushing device for the disposal of body fluid wastes.
- 6.5.2.15 The clean area shall have adequate counter space for receiving washed equipment for storage or wrapping.
- 6.5.2.16 There shall be a sink dedicated to hand washing or alcohol hand rub available in the reprocessing area.

6.5.3 High Level Disinfection (HLD)

- 6.5.3.1 The HLD product used shall have a Drug Identification Number (DIN) from Health Canada.
- 6.5.3.2 HLDs shall be prepared and used correctly to achieve the manufacturer's recommended dilution and time of immersion required to attain HLD.
- 6.5.3.3 When preparing HLD solutions, sources of extrinsic contamination (contaminated containers/preparation area) shall be prevented.
- 6.5.3.4 HLD concentration shall be checked daily at a minimum with an appropriate chemical test strip; and shall be discarded/changed if the concentration is less than the minimum effective concentration (MEC).
- 6.5.3.5 The HLD product shall be discarded/changed when the shelf life recommended by the manufacturer is reached.
- 6.5.3.6 There shall be a log kept of dates when HLD is changed.
- 6.5.3.7 Test strips shall not be used past the expiry date listed on the container.

- 6.5.3.8 There shall be a quality control procedure for checking test strips each time a new bottle is opened and shall be performed according to the manufacturer's recommendation.
- 6.5.3.9 A log shall be kept of the quality control procedure on test strips.
- 6.5.3.10 Rinsing of medical equipment following HLD shall be performed with three separate rinses with clean water. Sterile or sub-micron filtered tap water is recommended.
- 6.5.3.11 All reprocessed equipment shall be stored in a manner to keep them clean and dry.

6.5.4 Thermal Disinfection of Semi-Critical Devices

- 6.5.4.1 Thermal disinfection equipment (e.g. pasteurizer, washer-disinfector) shall have a Health Canada Medical Device License.
- 6.5.4.2 Devices shall be cleaned and rinsed prior to pasteurization/thermal disinfection.
- 6.5.4.3 Air pockets shall be displaced from the load and all devices shall be completely submerged during the pasteurization cycle.
- 6.5.4.4 Devices shall be processed at a minimum temperature of 71°C with a contact time of 30 minutes.
- 6.5.4.5 If a washer –disinfector is used to terminally disinfect semi-critical devices, the efficacy of the washer-disinfector shall be validated for this purpose.
- 6.5.4.6 The washer-disinfector shall be equipped with accessory manifolds and attachments designed for the devices to be disinfected.
- 6.5.4.7 For each reprocessing cycle, the pasteurizer or washer-disinfector shall provide a permanent record of date, temperature, exposure time and confirmation that cycle parameters have been met.
- 6.5.4.8 Following pasteurization/thermal disinfection, devices shall be handled to prevent contamination and transferred to a HEPA filtered drying cabinet that is used only for the drying of disinfected devices.
- 6.5.4.9 The pasteurizer or washer disinfector is maintained according to manufacturer's instructions.

6.5.5 Sterilization

- 6.5.5.1 Flash sterilization shall only be used in emergency situations and must never be used for implantable devices.

- 6.5.5.2 All sterilization processes/equipment shall follow the manufacturer's instructions for installation, operation and preventative maintenance of equipment.
- 6.5.5.3 A log shall be kept of preventative maintenance performed on sterilization equipment.
- 6.5.5.4 Equipment to be sterilized shall be wrapped and secured in materials that allow sterilant penetration, and shall be appropriate to the sterilization method and provide a barrier to contamination.
- 6.5.5.5 Bowie Dick air removal test (high vacuum sterilizers only) shall be done daily and documented.
- 6.5.5.6 Each load shall be monitored with mechanical digital indicators. (time, temperature, pressure.)
- 6.5.5.7 Each load/package shall be monitored with the appropriate chemical indicators (internal and external).
- 6.5.5.8 A log shall be kept of mechanical indicator results.
- 6.5.5.9 If mechanical or chemical indicators suggest inadequate processing, the items shall not be used.
- 6.5.5.10 Sterilizers shall be monitored with the appropriate biological indicator each day the sterilizer is used. (With every load if sterilizing implantable devices.)
- 6.5.5.11 At least one unprocessed control biological indicator from each lot of biological indicators shall be incubated according to the biological indicator manufacturer's instructions and results documented.
- 6.5.5.12 If processed biological indicator is positive, the load shall be recalled and the equipment not used.
- 6.5.5.13 A log shall be kept of biological indicator results.
- 6.5.5.14 A log shall be kept of all maintenance and interventions associated with a positive biological indicator.
- 6.5.5.15 A log is kept of each sterilization cycle that documents load number and load contents.
- 6.5.5.16 Wrapped sterilized packages shall be labeled with a load number, sterilizer and date.
- 6.5.5.17 There shall be a process in place that clearly identifies a non-reprocessed piece of equipment from one that has been reprocessed.

- 6.5.5.18 The sterile storage area shall be well-ventilated and protected from dust, moisture, insects, and temperature (to avoid excessive humidity) extremes.
- 6.5.5.19 Critical equipment that is sterilized unwrapped shall be used immediately and not stored.
- 6.5.5.20 Semi-critical equipment sterilized unwrapped shall be stored in a clean, dry area until use.
- 6.5.5.21 Equipment shall be cleaned and dried before an unwrapped sterilization cycle. Lumens shall be flushed with sterile water prior to sterilization.
- 6.5.5.22 Sterility of unwrapped devices shall be maintained during removal from the sterilizer and direct transport to point of use. Sterilized wrapped goods shall not be handled until cooled to maintain sterility.
- 6.5.5.23 Supplies shall be stored off the floor.
- 6.5.5.24 Outside shipping cartons and any corrugated cardboard containers shall not be kept in the clean supply area. De-boxing of the cartons shall not be carried out in the clean area or in the patient care areas.
- 6.5.5.25 The following is a list of documents which describe guidelines for sterilization. They should be consulted as necessary but do not necessarily constitute CPSA standards.

Standards Reference List

The following is a list of documents used as reference in creation of the infection control standards. Facilities are not required to obtain these standards.

NOTE: Copies of the following Canadian Standards Association documents can be obtained by contacting the Canadian Standards Association at:

1707 94 Street
 Edmonton AB T6N 1E6
 Phone: 1-800-463-6727
 Fax: (780) 435-0998
www.csa.ca

CAN/CSA-Z314.3-09	Effective Sterilization in Health Care Facilities by the Steam Process
CAN/CSA Z314.7-03	Steam Sterilizers for Health Care Facilities
CAN/CSA-Z314.8-08	Decontamination of Reusable Medical Devices
CAN/CSA-Z314.10.110	Selection and use, gowns, drapes and wrappers in health care facilities.
CAN/CSA-Z314.10.2-10	Laundering, maintenance, and preparation of multiple-use gowns, drapes, and wrappers in health care facilities.
CAN/CSA Z314.14-10	Selection and Use of Rigid Sterilization Containers

CAN/CSA-Z314.15-10	Warehousing, Storage, and Transportation of Clean and Sterile Medical Devices
CAN/CSA-Z314.22-10	Management of Loaned, Shared, and Leased Medical Devices
CAN/CSA-Z317.13-12	Infection Control During Construction or Renovation of Health Care Facilities
CAN/CSA-Z314.23-12	Chemical Sterilization of Reusable Medical Devices
CSA PLUS 1173-12	Guide to the Selection and Use of Sterilization Indicators
CAN/CSA-ISO Z17664-06	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
Alberta Health – 2012	Standards for Cleaning, Disinfection and Sterilization of reusable Medical Devices for Health Care Facilities and Settings: http://www.health.alberta.ca/documents/IPC-Medical-Device-Cleaning-2012.pdf
Alberta Health - 2011	Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices http://www.health.alberta.ca/documents/IPC-Medical-Device-Single-Use-2011.pdf

6.6 Housekeeping and Waste Management

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

- 6.6.1 The premises shall be kept neat, clean, and free of waste material.
- 6.6.2 Handling of waste material shall comply with the Regional waste handling requirements.
- 6.6.3 Specifically trained housekeeping personnel should maintain an established housekeeping routine.
- 6.6.4 Personnel shall adhere to a written protocol for cleaning each operating room:
 - 1. Between cases
 - 2. At the end of the day
 - 3. Weekly
 - 4. Monthly
- 6.6.5 Wet mopping shall be used. Dry dusting and dry mopping are not acceptable.
- 6.6.6 Provisions shall be made for proper laundering of linen and washable goods.
- 6.6.7 Soiled linen shall be placed in containers and handled as little as possible.
- 6.6.8 Protective garments (e.g. leather gowns and leather gloves) should be worn to sort soiled linen.
- 6.6.9 All patient care linen shall be removed from the operating room after each use.

6.6.10 Clean linen shall be covered and stored away from soiled linen.

6.6.11 Garbage shall be collected, contained, stored, and disposed so as to prevent disease transmission.

7.0 Facility

7.1 Personnel Requirements

- 7.1.1 One individual shall be designated to have overall responsibility for all nursing and clinical personnel.
- 7.1.2 One individual shall be designated to have overall responsibility for the operating room policies and procedures.
- 7.1.3 The following delegated functions may be provided only by personnel who have received specific training in each procedure:
 - 1. Mixing of medications
 - 2. Administration of medications
 - 3. Documentation of medications administered to patients
 - 4. Monitoring of vital signs during a procedure (shall be a suitably trained registered nurse or physician - refer to Section 5.2.2).
 - 5. Recovering patients from general anesthesia, major regional blocks or IV sedation (shall be a suitably trained registered nurse or physician - refer to Section 5.4.2).
- 7.1.4 Health Care Provider level certified CPR with AED training:
 - a. All nursing and ancillary personnel (registered nurses, licensed practical nurses) that provide direct clinical care and are not required to have ACLS shall maintain active certification in Health Care Provider level certified CPR with AED training.
 - b. At least one physician in the facility shall maintain active certification in Health Care Provider level certified CPR with AED training when there are no anesthesiologists on site.

7.2 General/Physical Standards

- 7.2.1 The facility shall comply with all applicable building code and fire regulations.
- 7.2.2 The facility should be accessible to handicapped persons.
- 7.2.3 There shall be easy access by an ambulance and stretcher for transfer of emergency cases to the hospital. A letter indicating approval of the access routes by the local ambulance service is highly recommended and should be kept on file.
- 7.2.4 The facility shall be physically adequate for the procedures performed, with a layout conducive to safe and private patient care and patient flow.
- 7.2.5 The design of the facility shall provide for separate administration and patient waiting areas; operating room, recovery room, clean utility, dirty utility and non-sterile storage; staff clothing change and staff lounges.

- 7.2.6 The dirty utility (soiled) workroom shall be physically separated from other work areas.
- 7.2.7 Traffic control systems should provide a minimum of cross-traffic.
- 7.2.8 Safe accommodation permitting the monitoring of vital signs and initiation of emergency resuscitation procedures shall be provided for the induction of anesthesia if started outside the operating room.
- 7.2.9 Sterile and non-sterile areas shall be clearly demarcated.
- 7.2.10 The facility's doors and corridors shall be wide enough for stretcher access.
- 7.2.11 There should be a sufficient number of reception and waiting areas to accommodate patients, relatives, and escorts.
- 7.2.12 Appropriate conveyances such as wheelchairs and/or stretchers shall be readily available.
- 7.2.13 Emergency lighting source (battery-operated or emergency power source) shall be available in all patient waiting areas and washrooms as well as in patient care areas unless natural light is available.
- 7.2.14 Fire extinguishers shall be available according to local standards.
- 7.2.15 Adequate sterilization equipment shall be available and in working order (Refer to Standards for Infection Control).
- 7.2.16 Floors shall be smooth and washable. If individual tiles are used, they shall be sealed with a polyurethane sealant.

7.3 Administration Standards

- 7.3.1 Ownership of the non-hospital surgical facility shall be clearly identified to the CPSA.
- 7.3.2 There shall be a current written description of the organizational responsibility for the operation of the facility.
- 7.3.3 An organizational chart is recommended and should be updated as necessary and be available to all personnel.
- 7.3.4 The duties and responsibilities of all personnel in the facility should be outlined in current written job descriptions.
- 7.3.5 There shall be adequate space for administrative functions so as not to interfere with clinical care and support areas.

7.4 Operating Room Standards

- 7.4.1 There shall be at least one operating room that is used exclusively for surgery, so as to maintain the integrity of supplies, equipment and cleanliness.
- 7.4.2 The operating room shall be large enough to accommodate required equipment, surgical and anesthetic personnel, and assistants.
- 7.4.3 Except where procedures do not require a sterile field (e.g. dental cases), there shall be enough clear space to allow the surgeon and assistants, when sterile, to move around the operating room table to gain access to both sides of the patient without contamination.
- 7.4.4 Operating Room size requirements depend on projected equipment and use:
1. Operating room table/chair.
 2. Anesthetic machine.
 3. Anesthesiologist's chair or stool.
 4. Small equipment table.
 5. Anesthetic drug cart.
 6. Extra emergency equipment that may be required, e.g., stretcher, defibrillator.
 7. Examples of minimum sizes:
 - a. 3.5 x 5.0 meters with a side door.
 - b. 3.0 x 4.0 meters with an end door direct to Recovery Room.
- 7.4.5 Ceilings in operating rooms requiring a sterile field shall be constructed of a smooth washable surface.
- 7.4.6 There should be physical segregation, with doors between the operating room and the rest of the facility.
- 7.4.7 The operating table/chair shall permit patient restraints and Trendelenburg positioning.
- 7.4.8 The operating room table/chair shall be suitable for the procedures performed including:
1. Adequate range of movement for anesthetic procedures.
 2. Adjustable headrest to facilitate intubation.
- 7.4.9 Suitable surgical lighting and emergency lighting sources shall be available.
- 7.4.10 Electrical outlets shall be accessible and adequate for all necessary equipment. Extension cords shall be appropriately rated and used in a safe manner.
- 7.4.11 There should be backup power for anesthetic carts, ventilators, and surgical equipment if this equipment is used.
- 7.4.12 Adequate suction for use exclusively by the anesthesiologist shall be available in the O.R.

7.5 Recovery Room Standards

- 7.5.1 There shall be a recovery room which is separate from the operating room if surgical cases are carried out while other patients are recovering from anesthetics or IV sedation.
- 7.5.2 The size of the recovery room will depend on projected use:
1. It shall 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.
 2. It shall allow easy access for transfer of a patient to or from a stretcher and performance of emergency procedures.
 3. Examples of minimum sizes:
 - a. 2 stretchers - minimum 2.4 x 2.7 meters with an end door.
 - b. 1 stretcher - 1.4 x 2.4 meters with a side entrance + 1 recliner (separate supervised space).
- 7.5.3 Suction and oxygen shall be readily available in the recovery area.
- 7.5.4 There shall be ready access to a sink for hand washing.
- 7.5.5 There shall be electrical outlets available to supply power to monitoring equipment if needed. Extension cords shall be appropriately rated and used in a safe manner.
- 7.5.6 An emergency lighting source shall be available in case of a power failure unless natural light is available.

8.0 Equipment/Supplies

All medical equipment/devices that are:

- a. class I shall require an establishment license (MDEL) issued by Health Canada Medical Devices;
- b. class II or higher shall have a medical device license issued (MDL) by Health Canada medical Devices.

8.1 Anesthetic and Resuscitation Equipment

(see Patient Care 5.2.3, 5.2.4, 5.2.5 & 5.2.6 on page 13)

8.2 Anesthetic Gas Equipment

- 8.2.1 All equipment for the administration of anesthetics shall be readily available, clean and properly maintained.
- 8.2.2 Flammable and explosive anesthetics shall not be used in the facility
- 8.2.3 Anesthetic materials shall be well-organized and anesthetic drugs properly stored.
- 8.2.4 The following is a list of documents which describe the standards for anesthetic equipment. They should be consulted when necessary but do not necessarily constitute CPSA standards.

NOTE: Copies of the following documents can be obtained by contacting the Canadian Standards Association at:

1707 94 Street
 Edmonton, AB T6N 1E6
 Phone: 1-800-463-6727
 Fax: (780) 435-0998

CAN/CSA Z.32.2-M89	Electrical Safety in Patient Care Areas
CAN/CSA Z.32.4-M86	Essential Electrical Systems for Hospitals
CAN/CSA Z.5361-94	Tracheal Tubes
CAN/CSA Z.7228-94	Tracheal Tube Connectors
CAN3 Z.168.3-M84	Anesthetic Machines
CAN/CSA Z.5360-94	Keyed Filling Devices Applied to Anesthetic Equipment
CAN/CSA Z.168.5.1	Anesthesia Ventilators
CAN/CSA Z.168.5.2-M1991	Critical Care Ventilators
CAN/CSA Z.168.6-M89	Oxygen Analyzers
CAN/CSA Z.8382-94	Resuscitators
CAN3 Z.168.8-M82 (R1994)	Anesthetic Gas Scavenging Systems
CAN/CSA Z.168.9-92	Breathing Systems for Use in Anesthesia
CAN/CSA Z.305.1-92	Nonflammable Medical Gas Piping Systems
CAN/CSA Z.305.2-M88	Low-pressure Flexible Connecting Assemblies for Medical Gas Systems

CAN/CSA Z.305.3-M87	Pressure Regulators, Gauges and Flow Metering Devices
CAN3 Z.305.4-M85	Qualifications for Medical Gas Testing Agencies
CAN/CSA Z.305.5-M86	Medical Gas Terminal Units (Outlets)
CAN/CSA C22.1	Canadian Electrical Code, Part I, Hospital Patient Care Areas, Sections 24, 52
CAN/CSA C22.2	Medical Electrical Equipment
CAN/CSA Z7396.1-09	Medical Gas Pipeline Systems-Part 1: Pipelines for medical gases and vacuum

- 8.2.5 There shall be adequate valving to ensure shut-off in case of an emergency and for maintenance of the main pipeline.
- 8.2.6 There shall be local zone shut-off valves for isolation of specific areas.
- 8.2.7 There shall be pressure relief valves to safely vent excessive pressures in all pressurized medical gas systems at all pressure levels.
- 8.2.8 There shall be pressure gauges and an electrical alarm system to ensure continuous surveillance of pipeline pressures.
- 8.2.9 The anesthetic circuit shall have a functioning low-pressure alarm if a positive pressure ventilator is used.
- 8.2.10 An oxygen analyzer (with a low oxygen concentration alarm) shall be located in the patient circuit.
- 8.2.11 A pressure gauge shall be located in the patient circuit.
- 8.2.12 An effective anesthetic gas scavenging system shall be employed.
- 8.2.13 An adjustable pressure-limiting valve ("pop-off" valve) shall be included in the circuit.
- 8.2.14 A reservoir bag and mount shall be included in the circuit.
- 8.2.15 All medical gas equipment including anesthetic machine, vaporizers, ECG and other monitors, and defibrillators shall be serviced and calibrated at least annually by a qualified person. There shall be documented evidence of this review.
- 8.2.16 Connections in medical gas systems shall be non-interchangeable between gases. This includes large cylinder to wall installations, wall to hose, hose to anesthetic machine and small cylinder to machine (pin-indexed). Gas hoses, cylinders, flow meters and control valves shall be color coded and/or marked with name or chemical symbol at all junctions.
- 8.2.17 All anesthetic gas delivery systems shall contain fail safe systems ensuring a minimum of 25% oxygen. The failsafe shall be an **in-ratio** system: the failsafe allows the gas to fall off in the last proportion set by the operator (and this should activate at about 5-6 p.s.i.).

8.2.18 A second supply of oxygen (normally a spare cylinder) with pressure gauge, regulator and wrench shall be available.

8.2.19 Vaporizers shall be appropriate to the particular liquid agent in use. They shall be pin-indexed.

8.3 Drugs

8.3.1 There shall be a drug inventory record and a policy requiring periodic assessment of all drugs kept in the facility.

8.3.2 Drugs shall be stored in a manner suitable for their security, re-stocking, and renewal of out-dated supplies.

8.3.3 Drugs shall be stored according to the manufacturer's recommendations (e.g. refrigeration as necessary).

8.3.4 Drugs dispensed to patients at the time of discharge shall be recorded on the clinical record, and verbal and written instructions for their use given to the patient or his/her accompanying adult.

8.3.5 Refer to Appendix A for lists of required and recommended drugs.

8.4 Controlled Substances/Narcotics

8.4.1 One qualified individual (an RN, an LPN with medication skills, a physician or a dentist) shall be designated to have overall responsibility for ensuring that all controlled substances are handled in a manner that permits full auditing of the substances from acquisition through to patient administration.

8.4.2 There shall be a log of controlled substances received by the facility that includes the name and quantity of the drug, and the date received.

8.4.3 All controlled substances shall be kept in a designated secure and locked storage cabinet.

8.4.4 The following information shall be recorded on the log for each use of a controlled substance administered:

- Patient name
- Drug name and amount removed from inventory
- Date
- Name of the person who administered the drug

8.4.5 On each day that controlled substances are used, there shall be an end-of-day balance of the inventory of controlled substances via physical count, verified by the signatures of two qualified staff members.

8.4.6 Investigations conducted as a result of any discrepancies shall be documented.

8.5 Laser Registration

8.5.1 The Radiation Protection Act and Regulations shall apply.

8.5.2 All class IIIb and IV laser equipment as defined in the Radiation Protection Act and Regulations, shall be registered for use in Alberta with the College of Physicians & Surgeons of Alberta.

8.6 Blood Products

8.6.1 Facilities administering blood or blood products shall have a transfusion medicine consultant, as approved by the CPSA who will ensure that there is compliance (where applicable) with Canadian Society of Transfusion Medicine (CSTM) standards. This shall include but is not limited to:

1. Storage of blood/blood products
2. Patient identification procedures
3. Issuing and handling of blood/blood products
4. Traceability (i.e. look-back/trace-back)
5. Reporting of adverse reactions
6. Utilization

8.7 Bone, Bone Product, Cells and Tissues

8.7.1 Donation to Tissue Banks

1. An NHSF which collects tissues from patients for a tissue bank shall do so under a written agreement with an approved tissue bank.
2. The agreement shall specify policies and procedures to be followed in accordance with applicable provincial and national standards and the American Associations of Tissue Banks. (eg. Packaging, labeling, transfer)
3. Donations of tissue will be an integral part of the consent and preoperative teaching of patients who are prospective donors.

8.7.2 Use of Allogenic Bone, Bone Products, Cells and Tissues in NHSFs

1. An NHSF shall only use allogenic bone, bone products, and tissues acquired from sources reviewed and deemed acceptable by the Comprehensive Tissue Centre in Edmonton or the Southern Alberta Tissue Program in Calgary.
2. The NHSF shall document compliance with all shipping, transportation and timing arrangements necessary to maintain the integrity and safety of all products received for use in patients.
3. Documentation in the health record and a central log for transplanted tissues shall include all information necessary for traceability.

4. Patients shall be given written information indicating they received an allogenic tissue or product.
5. All products shall be used only once and shall not be reprocessed, refrozen or repackaged.
6. All unused tissue and product shall be disposed as bio-hazardous waste.
7. The following references should be available on-site:
 - a. Guidance Document: Basic Safety Requirements for Human Cells, Tissue and Organs for Transplantation – Health Canada
 - b. Organ and Tissue Donation and Transplantation (OTDT) - Alberta Health, July 2003
 - c. Cells, Tissues, & Organs for Transplantation & Assisted Reproduction: General Requirements – CAN/CSA-Z900.1-03
 - d. Tissues for Transplantation – CAN/CSA-Z900.2.2-03
 - e. Ocular Tissues for Transplantation – CAN/CSA-Z900.2.4-03

9.0 Documentation/Records

There shall be an appropriate administrative structure to provide for the documentation, storage, and retrieval of all necessary patient information.

9.1 Personnel Records

Appropriate personnel records shall be maintained in confidential files and should include:

1. A completed application form.
2. A record of having been oriented to the facility and of having received education in his/her assigned duties.
3. Evidence of required credentials (e.g. RN).
4. Performance evaluations.
5. Evidence of required certifications (e.g. cardiopulmonary resuscitation).
6. Vaccination and immune status records.
7. Record of eye examinations as required by CSA Standard Z386-92 - Laser Safety in Health Care Facilities (if applicable).

9.2 Medical Records

- 9.2.1 The facility shall maintain an operative log book which contains the name of the patient, the date, the procedure performed, and the name of the surgeon(s) and anesthesiologist
- 9.2.2 Patients undergoing surgery shall have a clinical record that originates with the initial visit or that is incorporated into the ongoing clinical record of the patient.
- 9.2.3 The clinical record shall follow a uniform format within the facility and be accurate, complete, and legible.
- 9.2.4 The clinical record shall contain the following:
 1. Consent for the procedure and anesthetic signed by the patient and witnessed.
 2. Pre-operative record which includes:
 - a. A medical history and physical examination which includes the findings indicating the necessity for the proposed treatment.
 - b. Complete record of current medications.
 - c. Weight.
 - d. Allergies.
 - e. Laboratory results (as indicated).

3. Anesthetic record - when a general anesthetic, IV sedation or major regional anesthesia is administered, an appropriate record shall be kept which includes the following:
 - a. Pre-anesthetic assessment.
 - b. All drugs administered including dose, time, and route of administration.
 - c. Fluids administered.
 - d. Fluids lost (e.g. blood, urine) where it can be measured.
 - e. Measurements made by the required monitors, including blood pressure, heart rate and oximetry at least every five minutes.
 - f. Complications and incidents (where applicable).
 - g. The name of the anesthesiologist and the surgeon.
 - h. Anesthetic start and stop time.
 - i. Throat pack insertion and removal (verified by a second worker and documented on the anesthetic or perioperative record) (where applicable).

4. Peri-operative (nursing) record which includes:
 - a. Name of all procedure(s) actually performed
 - b. Name of surgeon(s), anesthesiologist and other personnel
 - c. Additional details as appropriate e.g. instrument counts, tourniquet time, implants used, solutions used, patient position, surgical time, disposition of tissues removed, drugs administered, any dyes or agents used etc.
 - d. Unexpected events

5. An operative note shall be documented and signed by the surgeon, on the facility patient care record, on the same day of the procedure, and shall include:
 - a. the type of procedure performed;
 - b. a description of surgical complications/findings

6. A final operative report, which should be generated on the date of the operation, and a pathology report of relevant tissue removed, are the responsibility of the surgeon who should retain them with his/her other medical records unless otherwise arranged within the facility.

7. Post-anesthetic care (PARR) record which includes:
 - a. Date and time of admission.
 - b. Initial and periodic measurements of blood pressure, pulse, respirations, temperature, level of consciousness, oximetry and general status.
 - c. Any medications administered, including dose, time, date, route, site, reasons, and effects.
 - d. Any treatments given and effects of such treatments.
 - e. Findings on an objective scoring system for discharge.
 - f. The name of the recovery room nurse.

8. The facility clinical record(s) consisting of:
 - a. pre-operative care,
 - b. anesthetic care,
 - c. peri-operative care,
 - d. surgeons operative note,
 - e. post-anesthetic care; are the property of the facility and the responsibility of the Medical Director.

9.3 Incident Reports

NOTE: **Incident** defined as untoward, undesirable and usually unanticipated events or outcomes that caused harm or risk of harm to a patient, employee or visitor in the facility. An incident may or may not be a result of a deviation from the normal process of care.

9.3.1 There shall be an internal process to document and investigate incidents. An incident report shall be completed which includes the following:

1. Name, age, and sex of the person involved in the incident.
2. Name of witness(es) to the incident.
3. Date and type of procedure (if applicable).
4. Date and time of incident.
5. Nature of the incident and treatment rendered.
6. Analysis of reasons for the incident.
7. Outcome.

9.3.2 There shall be a process to document corrective action taken if applicable.

9.3.3 A copy of all incident reports shall be kept in a separate file.

9.3.4 All incident reports shall be reviewed at least annually by the Medical Director.

9.4 Reportable Incidents

(Reportable incidents, as defined below, are also known as “significant mishaps” in the Health Care Protection Regulations of Alberta.)

9.4.1 Medical Examiner

1. In the event of a death within the facility, the Medical Examiner shall be notified prior to moving the body or removal of any lines or tubes from the body.

9.4.2 Registrar - College of Physicians & Surgeons of Alberta

1. The Medical Director shall notify the College of Physicians & Surgeons of Alberta (Quality of Care Department) within one working day after the discovery of any reportable incident, including:
 - a. Deaths within the facility or within 10 days of the procedure.

- 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 (See also discharge instructions to patients).

NOTE: When notified of an unexpected admission of a patient to hospital within 10 days of the procedure in the NHSF, the Registrar may determine that written notification is not required when the reason given for admission to hospital is not related to the services provided in the facility.

- d. Clusters of infections among patients treated in the facility.
 - e. Any procedure performed on the wrong patient, site or side.
2. Within **two weeks** of notification, the following shall be submitted to the CPSA:
 1. Completed reportable incident form signed by the Medical Director and the physician most involved in the case
 2. Copy of the facility clinical record
 3. The Registrar will review the circumstances with the Medical Director and may consult with other practitioners to determine the risk of harm to patients. If necessary, the Registrar may suspend the accreditation of any facility on a suspicion of continuing risk. An investigation of the facility will then be initiated as soon as is reasonably possible.

9.5 Storage and Retention

Medical records and operating room logs and incident/complication reports shall be retained for a minimum of ten years following the date of the incident/complication; or, in the case of minors, at least until two years past the age of majority or for ten years, whichever is longer.

Medical records of the ongoing care of a patient shall be kept for a minimum of ten years following the last date of service to the patient; or, in the case of minors, at least until two years past the age of majority or for ten years, whichever is longer.

Notwithstanding the above, the records of all dependent adults shall be kept indefinitely.

The service provider shall maintain safeguards to protect the confidentiality of patient records and to protect against reasonably anticipated threats or hazards to the security, integrity, loss or unauthorized use, disclosure, modification or unauthorized access to health information. This applies to records in paper or electronic format.

9.6 Annual Report to the CPSA

The facility will submit annually to the CPSA on the subscribed form the following information regarding services provided in the facility during the previous calendar year.

9.6.1 The number of each type of surgical procedures performed in the facility.

9.6.2 “Dental” procedures shall be reported as the number of anesthetic procedures.

9.6.3 The name of any physicians whose privileges in the facility were not renewed or were reduced and the reason for it.

(The Medical Director has an ethical obligation, as does any physician, to notify the CPSA immediately if he or she is aware of a colleague who may be practicing in a manner that could be harmful to patients.)

10.0 Safety Standards

10.1 General Facility and Patient Safety

10.1.1 Mock drills to prepare employees for emergency situations such as cardiac arrest, shall be conducted at least every six months. The type of drill and employee attendance shall be documented.

10.1.2 The facility shall have plans for emergencies such as:

1. Fire
2. Power Loss
3. Equipment Failure
4. Cardiopulmonary Arrest
5. Anaphylaxis
6. Malignant Hyperthermia
7. Unauthorized Intruder
8. Emergency Transfer to Hospital

10.1.3 There should be documented evidence that all personnel, including medical and dental personnel, are familiar with emergency plans.

10.1.4 Smoking shall be prohibited in the patient care, sterile, and preparation areas of the facility.

10.1.5 There shall be a documented policy and procedure in place for handling patient concerns/complaints.

10.1.6 The Medical Director shall ensure that the process for lodging concerns is readily available and apparent to patients and the public.

10.2 Medical Compressed Gases

10.2.1 All new or modified non-flammable medical gas piping systems shall be designed, installed, and tested in accordance with the Alberta Building Code.

10.2.2 All non-flammable medical gas piping systems shall be verified by a Safety Code Officer with Building Group 5-C Certification **prior** to being put into service. A letter of verification shall be kept on file.

10.2.3 All non-flammable medical gas piping systems shall be tested at least every six months for verification of pressure at every outlet with a flow, and verification of vacuum pressure for vacuum outlets. Documentation of the semi-annual checks shall be recorded by a qualified anesthesiologist or certified technologist and a letter of verification shall be kept on file.

*The following list shall be posted for personnel information:

10.2.4 Never permit oil or grease to come in contact with cylinders, valves, regulators, gauges, or fittings.

- 10.2.5 Store cylinders in designated places away from the operating field where they will not be knocked over or damaged by passing or falling objects.
- 10.2.6 Cylinders shall be protected from direct sunlight.
- 10.2.7 Cylinders in use shall be securely chained to a solid object, or in a secure base, to prevent their tipping.
- 10.2.8 Full cylinders shall be used in rotation in the order that they are received from the supplier.
- 10.2.9 Never use cylinders for rollers, supports or for any purpose other than to carry gas.
- 10.2.10 Where caps are provided for valve protection such caps shall be kept on cylinders except when cylinders are in use.
- 10.2.11 Never tamper with the safety devices in valves or cylinders.
- 10.2.12 Never attempt to repair or alter cylinders or refill cylinders.
- 10.2.13 Never attempt to use gases in cylinders not bearing a contents label or cylinder having a label all of which is not completely legible.
- 10.2.14 Never use oxygen from a cylinder without reducing the pressure through a suitable regulator intended for that purpose only.
- 10.2.15 Never permit oxygen to enter the regulator suddenly. Open the cylinder valve slowly.
- 10.2.16 Fully open the valve when the cylinder is in use.
- 10.2.17 Never interchange oxygen regulators, hose, or other appliances with similar equipment intended for use with other gases.
- 10.2.18 Never hold a gloved hand over the outlet to test the pressure. A serious burn may result.
- 10.2.19 Never heat cylinders above room temperature or allow a flame to play on them.
- 10.2.20 Never use oxygen in place of compressed air as a pressure medium to blow out obstructed pipelines, to operate pneumatic tools or to build up pressure in tank containing oils or other flammable materials. Nitrogen is the preferred gas for blowing out pipelines. Clean compressed air free of water or oil may also be used.
- 10.2.21 Oxygen shall never be used to blow dust out of clothing or to freshen air in a closed place. Serious burns may result from such practices.
- 10.2.22 CLOSE ALL OXYGEN CYLINDER VALVES WHEN THE CYLINDERS ARE EMPTY.

- 10.2.23 At the start of each operating day turn on oxygen regulator only, then turn oxygen on at the machine.
- 10.2.24 Before any maintenance or repair work is done in any building where general anesthetics are being administered and which would involve interrupting oxygen flow, the anesthesiologist shall be informed immediately and an oxygen analyzer shall be used to check that lines have not been switched. This does not apply to the periodic exchange of tanks.

10.3 Electrical

Electrical safety shall meet or exceed standards contained in the most recent version of the Canadian Electrical Code, as determined by a qualified contractor or assessor.

10.4 Fire

Fire safety shall meet or exceed standards contained in the most recent version of the Alberta Fire Code, as determined by a qualified contractor or assessor.

11.0 Quality Assurance and Improvement

Accreditation by the College of Physicians & Surgeons requires that quality assurance and improvement programs are in place so that high standards of patient care can be demonstrated. These programs should identify potential problems, determine the cause of problems, and implement actions to eliminate or improve them. Many of the components of these programs can be conducted by other staff but results should be reviewed at least annually by the Medical Director.

The following outline provides recommendations for a quality improvement program in non-hospital surgical facilities:

11.1 Structure

Examples:

11.1.1 Environment

1. Maintenance and space/facility requirements.

11.1.2 Equipment

1. Routine testing.
2. Review of record maintenance and service requirements.

11.1.3 Personnel

1. Numbers and types of personnel required.
2. Performance reviews.

11.2 Process

Examples:

11.2.1 Clinical Care

1. Review of procedures in light of new technology or practice guidelines.
2. Case reviews/audits with description of problems and recommendations to prevent future occurrences.

11.2.2 Mock Trials

1. Review of safety procedures and results of mock drills.

11.2.3 Medical Records

1. Audits of completeness, legibility, etc.

11.3 Outcome

Examples:

11.3.1 Infection Rates

11.3.2 Incidents/Complications

11.3.3 Case Review Audits

11.3.4 Patient Satisfaction

12.0 Manuals

Policies and Procedures should reflect these and other published standards of the CPSA 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 NHSFs.

12.1 Policy Manual

- 12.1.1 Policy statements should be consistent with the goals of the organization.
- 12.1.2 Policies should be developed for personnel, office, and procedures.
- 12.1.3 The Medical Director or a designated person shall ensure that all necessary policies are established, maintained, written, and implemented.
- 12.1.4 All policies shall be signed by the Medical Director or appropriate designate as developed.
- 12.1.5 A process for review and signature by the Medical Director or appropriate designate shall occur at least every 4 years.
- 12.1.6 The policy manual shall be available to all relevant staff. If there is more than one copy, then each shall be numbered to ensure changes are made in identified manuals. One copy should be identified as the master copy.
- 12.1.7 As changes are made, copies of past policies shall be kept on file for legal purposes.
- 12.1.8 Each policy should be complete within its identified numbered pages.
- 12.1.9 The policy format should be consistent, standardized and easily identified as a policy.
- 12.1.10 Header information on each policy should include (sample format - Appendix B):
 - 1. Facility name.
 - 2. Title of policy.
 - 3. Original date of policy - which is carried forward on each review.
 - 4. Revision dates - which should also be carried forward with changes.
 - 5. The last revision date on each page.
 - 6. The next expected revision/review dates (not more than 2 years).

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

1. Admission Criteria;
 - a. Operating room
 - b. Recovery Room
2. Bomb Threat (for facilities where this may be a risk);
3. Critical Incident Management;
 - a. Patients
 - b. Personnel
 - c. Equipment/Facility
4. Death;
 - a. Notification, Management of
5. Discharge Criteria;
 - a. Operating Room
 - b. Recovery Room
6. Documentation/Record Requirements;
 - a. Health record/chart
 - b. Operating room nursing
 - c. Anesthesiologist
 - d. Surgeon
 - e. Recovery room
 - f. Quality assurance
 - g. Statistics
 - h. Incidents/complications
7. Emergency Patient Transfer
8. Fire/Evacuation
9. Infection Control
10. Medical Record Management
11. Monitoring Protocol
 - a. Preoperative
 - b. Intraoperative
 - c. Postoperative
12. Office Policies

13. Organizational Chart
14. Personnel:
 - a. Content and access to personnel files
 - b. Occupational Health requirements
 - c. Orientation and education
 - d. Responsibilities
 - e. Job descriptions
 - f. Employee rights
15. Grounds for immediate dismissal.

12.2 Procedure Manual

- 12.2.1 Current procedure manual(s) should be readily available in the appropriate work area.
- 12.2.2 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.
- 12.2.3 The Medical Director or a designated member of personnel should ensure that manuals are current and accurate.
- 12.2.4 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.
- 12.2.5 All physicians involved with the procedures should have knowledge of the written procedures and should be involved in changes to the procedures each provides.
- 12.2.6 Related information should be consolidated in one section.
- 12.2.7 All procedures shall be signed by the Medical Director or appropriate designate as developed.
- 12.2.8 A process for review and signature by the Medical Director or appropriate designate shall occur at least every 4 years,
- 12.2.9 The list of procedures shall be those approved for the facility.
- 12.2.10 A process to assess compliance with procedures should be in place.
- 12.2.11 Vendor manuals should be attached/located with or near each piece of equipment. Complex equipment should have quick reference summaries attached, e.g. electrosurgery and phacoemulsifier devices.

- 12.2.12 All personnel shall 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.
- 12.2.13 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.
- 12.2.14 A communication process should be established to inform the necessary personnel of changes in procedures, updates, and new procedures.
- 12.2.15 Where significant changes to a procedure manual are made, the administrative area shall keep a file of the previous procedure, for legal reasons.
- 12.2.16 A standard format should be developed and used for all procedures. It should include, but is not limited to (sample format - Appendix C):
1. Name of procedure
 2. Principle/purpose of procedure
 3. Patient preparation
 4. Equipment/supplies needed
 5. Equipment calibration steps and trouble shooting if applicable
 6. Special equipment cleaning/sterilizing
 7. Steps of procedure in sequential order
 8. Utilization of pictures and diagrams where helpful
 9. Rationale for steps in procedure included where helpful
 10. Limitations/potential complications
 11. Special safety precautions
 12. Normal result expected - age range and sex where applicable
 13. Clinical significance
 14. Critical values
 15. Reporting of results required
 16. Reference sources e.g. CSA documents, Provincial/National Standards, Vendor reference source
 17. Comments section for special notes
 18. Date procedure was established
 19. Last date of review/revision
 20. Source of approval (responsible person) - with actual signature
- 12.2.17 The topics of Procedure Manuals should include, but are not limited to;
1. Aseptic Practices:
 - a. Processing, handling, storage and control sterile goods
 - b. Traffic restrictions
 - c. Washing, storage, folding, reprocessing of fabrics for the operating room
 - d. Packaging material

2. Infection Prevention:
 - a. Cleaning procedures - instruments, furniture, materials, devices
 - b. Containment of soiled materials
 - c. Hand washing
 - d. Hand scrubbing protocols
 - e. Handling of infectious wastes (blood/body fluids)
 - f. Handling of known infected/contagious patients
3. Housekeeping (in the operating room) between cases, daily, weekly, and monthly;
 - a. Restriction of infected/contagious personnel
 - b. Universal precautions
 - c. Protective devices/equipment
 - d. Soap/detergent/antiseptic use and dispensing (including approved agents)
 - e. Transport of soiled materials
4. Cardiopulmonary Arrest:
 - a. Management of
5. Dress Code:
 - a. Identification of personnel
 - b. Operating room dress code
 - c. Dress code in non-operating room areas
 - d. Protective clothing
6. Emergency Patient Transfer:
 - a. Process to be followed
7. Safety:
 - a. Handling and disposal of sharps
 - b. Handling of waste products
 - c. Process for personnel immunization
 - d. Process for personnel injury at work
 - e. Process for management of needles/sharp injury with contaminated items
 - f. Process for handling radioactive or dangerous/carcinogenic drugs/chemicals

8. Equipment Sterilizers:
 - a. Operating instructions for each unit
 - b. Process for record keeping for each load with parameters to be recorded
 - c. Process for the use and recording of thermal, chemical and biological indications
 - d. Process for frequency and method of cleaning units
 - e. Process for preventative maintenance
 - f. Process for breakdown and alternative operations

9. Patient Care: (General and procedure specific)
 - a. Pre-facility visit requirements
 - b. Admission criteria
 - c. Pre-operative prep - by procedure/group of procedures
 - d. Patient chart requirements
 - e. Patient complaints

10. Documentation details:
 - a. Supplies and equipment required
 - b. Positioning procedures
 - c. Skin preparation for surgery
 - d. Draping procedures
 - e. Intra-operative care
 - f. Post-operative care in theatre
 - g. Management of complications
 - h. Discharge teaching for each procedure/group procedure (patient and surgeon specific)

11. Recovery Room:
 - a. Admission criteria and care
 - b. Documentation details
 - c. Management of complications
 - d. Discharge criteria
 - e. Call for ambulance/crisis detail

12. Work Station Duty Lists:
 - a. Specific for each specific role, work area

12.3 Equipment Manual

12.3.1 Equipment

This manual should include, as a minimum, for each piece of equipment:

1. A list of contact personnel and phone numbers
2. Manufacturer operating and troubleshooting instructions
3. Preventative maintenance schedule and log
4. Record of repairs

12.3.2 Computer

This manual should include, as a minimum:

1. List of contact personnel and phone numbers
2. Availability of software and back-up disks or tapes
3. Schedule for developing back-up discs or tapes
4. Procedure to be used in case of computer failure
5. List of personnel who have access to information and software security codes
6. Guidelines for protection of confidentiality of patient data
7. Location of software source code listing and, where appropriate, details of signal acquisition and processing algorithms should be described

12.4 Safety Manual

This manual should include, as a minimum, the following sections:

1. General Safety
2. Medical Compressed Gases
3. Infection Control
4. Biohazardous Waste
5. Electrical
6. Fire
7. Medical Emergencies

Appendix A - Non-Hospital Surgical Facility Drug Supply

1.0 Facilities Providing General Anesthesia and/or Major Regional Blocks (except retrobulbar anesthesia)

These drugs may be stored in the facility or be brought in by the anesthesiologist.

1.1 Required drugs:

1.1.1 Basic list for emergency treatment:

1. Oral
 - a. Acetylsalicylic acid (ASA) non-enteric coated chewable tablets and
 - b. Nitroglycerin spray.
2. Inhaled
 - a. Salbutamol (with spacer device)
3. Intravenous
 - a. Atropine;
 - b. Benzodiazepine, either midazolam or diazepam;
 - c. Beta-blocker;
 - d. Dantrolene Sodium, enough for the first dose, when depolarizing muscle relaxants and/or volatile anesthetic gases are used;
 - e. Diphenhydramine;
 - f. Epinephrine;
 - g. Ephedrine, subcutaneous and intravenous;
 - h. Furosemide;
 - i. Glucose 50%;
 - j. Hydralazine or nifedipine;
 - k. Hydrocortisone;
 - l. Lidocaine, bolus doses & one infusion bag;
 - m. Naloxone, when parenteral narcotics are used;
 - n. Neostigmine or equivalent, when non-depolarizing muscle relaxants (except mivacurium) are used;
 - o. Phenylephrine;
 - p. Procainamide;
 - q. Short-acting muscle relaxant;
 - r. Sodium bicarbonate, including pediatric vials if facility treats children;
 - s. Sterile water or saline for dilution;
 - t. Verapamil or adenosine.

1.2 Recommended drugs:

1.2.1 Intravenous

1. Amiodarone
2. Flumazenil
3. Vasopressin

2.0 Facilities Providing IV Sedation, Retrobulbar Anesthesia, and/or local or topical sedation.

2.1 Required Drugs:

2.1.1 Basic list for emergency treatment:

1. Oral
 - a. Acetylsalicylic acid (ASA) non-enteric coated chewable tablets;
 - b. Nitroglycerin spray.
2. Inhaled
 - a. Salbutamol (with spacer device)
3. Intravenous
 - a. Atropine;
 - b. Benzodiazepine, either midazolam or diazepam;
 - c. Diphenhydramine;
 - d. Epinephrine, subcutaneous and intravenous;
 - e. Naloxone, when parenteral narcotics are used.

Appendix B - Policy Manual - Sample Format

Facility Name

POLICY NO:

Page _____ of _____

Last Revision / Review Date:

Next Review Date:

Source:

Approved By:

(Medical Director's Signature)

Policy Title

Philosophy:

Policy Statement:

References:

Appendix C - Procedure Manual - Sample Format

Facility Name

Date of Original Procedure: _____ Procedure No: _____

Last Review / Revision Date: _____ Page _____ of _____

Next Review Date: _____

Source: _____

Medical Director / Designate Signature _____

Procedure

General Description: _____

Patient Preparation: _____

Procedure Steps:

Rationale:

- | | <u>Procedure Steps:</u> | <u>Rationale:</u> |
|----|-------------------------|-------------------|
| 1. | _____ | _____ |
| 2. | _____ | _____ |
| 3. | _____ | _____ |
| 4. | _____ | _____ |
| 5. | _____ | _____ |

Equipment: (Procedure to setup, calibrate, recording required) _____

Precautions/Safety Measures: _____

Comments/Diagrams: _____

Specific Surgeon Needs: _____

References: _____

Appendix D

Recommended practices for cleaning and sterilizing intraocular surgical instruments

From the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses

Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS. These substances can be divided into extraocular substances that inadvertently enter the anterior chamber during or after surgery (topical anti-septic agents,^{1,2} talc from surgical gloves,^{3,4} topical ophthalmic ointment⁵), products that are introduced into the anterior chamber as a part of the surgical procedure (anesthetic agents,^{6,7} preservatives,⁸⁻¹¹ inappropriately reconstituted intraocular preparations, mitomycin-C,¹³ intraocular lens¹⁴), and irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of inadequate or inappropriate instrument cleaning (denatured ophthalmic viscosurgical devices [OVDs] [Sutphin JE, Papadinos TJ. IOVS 1989; 30:165 ARVO Abstract 8],¹⁵ detergents,¹⁶ heat stable endotoxin from overgrowth of gram-negative bacilli in water baths of ultrasonic cleaners,^{17,18} degradation of brass containing surgical instruments from plasma gas sterilization,¹⁹ and impurities of autoclave steam²⁰).

Whereas opportunities exist to prevent TASS resulting from extraocularly or intraocularly applied products by product withdrawals, product communications, and compounding alerts, preventing TASS by appropriate management of intraocular surgical instruments is a challenge that must be repeated with each cycle of cleaning and sterilization of cataract surgical instruments at every cataract surgical facility. In fact, this challenge is not always satisfactorily addressed, resulting in single-facility outbreaks of TASS that frequently subside when the cleaning and sterilization steps are improved (N. Mamalis, MD, H. Edelhauser, PhD, personal communication, September 2006). Careful review of a number of facilities

reporting cases of TASS to the Intermountain Ocular Research Center at the University of Utah in the spring of 2006 identified many opportunities to lower the risk for TASS through improving the steps of the cleaning and sterilization process. The goal of these recommended practices for cleaning and sterilizing intraocular surgical instruments is to prevent single-facility outbreaks of TASS related to contaminated or degraded instruments. It is also hoped that the availability of recommended practices could facilitate the identification of causes of TASS and resolution of single-facility outbreaks of TASS when they occur. The recommendations have been written to be generic enough to enable appropriate application at all facilities performing cataract surgery, recognizing that differences in procedures and activities exist between surgical facilities.

The recommended practices are derived largely from existing, evidence-based general recommendations for cleaning and sterilizing all surgical instruments,^{22,24} from evidence derived from published reports of single-facility outbreaks of TASS,^{3,4,15,20} and from directions for management of equipment provided by manufacturers. The challenge of preventing TASS is multifaceted. Relevant factors include the minute amounts of irritants needed to cause clinically significant postoperative inflammation of the anterior chamber, the frequency with which cataract surgery is performed on a daily basis across the country, the variety of instruments used, and the various requirements for cleaning different types of instruments. Consequently, these recommendations for cleaning and sterilization were developed by representatives of professional societies for cataract surgeons, ophthalmic and operating room nurses, and infection control, in collaboration

with manufacturers of intraocular cataract surgical instruments. Guidance was also provided by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration.

These recommended practices are not intended to address all requirements for sterilization and quality assurance of the sterilization process. They should be used in conjunction with current consensus guidelines from the Association for the Advancement of Medical Instrumentation (AAMI), the American Society of Ophthalmic Registered Nurses (ASORN) and the Association of perioperative Registered Nurses (AORN).^{22,24,30} The recommendations are believed to be relevant for instruments used in all intraocular surgical procedures, most of which are cataract surgical procedures; therefore, to expedite consistent and optimal instrument management, the recommendations are intended to apply to all intraocular surgical instruments. When recommendations for instrument management include cleaning without disinfection prior to sterilization, unsterilized instruments should be considered contaminated and therefore unsafe for handling unless appropriate barriers and precautions are used (eg, gloves and separation from environments in which disinfected items are handled).

The recommendations are divided into 2 sections. The first establishes general principles of cleaning and sterilization that must be addressed to prevent TASS. The second provides specific recommendations for cleaning and sterilizing intraocular surgical instruments.

GENERAL PRINCIPLES OF CLEANING AND STERILIZING INTRAOCULAR SURGICAL INSTRUMENTS

The instruments should be kept moist until the cleaning process begins to avoid drying of debris and QVD.^{23,25,26}

All debris inclusive of OVD should be removed.^{15,25,27}

Quality and volumes of water should be used as specified by manufacturer's directions for use (DFU) for suspension of detergents and for cleaning and rinsing instruments.^{22,23,28} The DFU for many intraocular instruments require or recommend sterile distilled or sterile deionized water for most cleaning steps. Sterile distilled or sterile deionized water are required for final rinsing.²⁵

Follow detergent and instrument manufacturers' DFU to ensure proper use of the detergent and to ensure comparability with the instruments.^{22,23,28}

Rinsing should remove all cleaning agents as well as

all debris loosened during the cleaning process.^{25,26,29} The method of sterilization applied to instruments should be approved by both the manufacturer of the sterilizer and the manufacturer of the surgical instruments. Sterilizers should be maintained in accordance with the manufacturer's recommendations.^{22,24}

Procedures for instrument cleaning and sterilization should be developed and written for each healthcare facility.^{22,23}

Adequate time should be provided to allow completion of all steps of cleaning and sterilization.^{22,23}

Staff training, competency validation, and periodic performance review should be implemented for each healthcare facility.^{22,23,30}

RECOMMENDATIONS FOR CLEANING AND STERILIZING INTRAOCULAR SURGICAL INSTRUMENTS

1. Adequate time for thorough cleaning and sterilization of instrumentation should be established.
 - a. Rigorous adherence to recommended procedures for cleaning and sterilizing surgical instruments should never be circumvented to save time or money.^{30,31}
 - b. Inventory of instruments should be sufficient to meet surgical volumes and to provide adequate time for completion of cleaning and sterilization.^{22,23}
 - c. Rash sterilization is designed to manage unanticipated, urgent needs for instruments. Flash sterilization should not be used to save time or as a substitute for sufficient instrument inventory.²²
2. For each piece of equipment, the manufacturer's DFU pertaining to cleaning and sterilization should be followed.²²⁻²⁴
3. Ophthalmic viscosurgical device solution, which can dry and harden within minutes, should not be allowed to dry on the instruments.²⁵
 - a. Instruments should be wiped with a dampened lint-free cloth and flushed and/or immersed in sterile water in the operating room (OR) immediately following use, in strict accordance with

- manufacturer's DFU for each instrument.^{23,24} Sterile water baths used for cleaning or soaking soiled instruments should be kept in areas removed from the operative field and removed from sites that maintain instruments needed to complete the surgical procedure.
- b. The DFU for some reused cannulated instrument specify the solution, volumes, and frequency for flushing of each lumen. Flushing should be completed as specified in the OR or in the decontamination area.^{23,24}
4. Whether they are used, instruments opened for a procedure should be transported from the OR in a closed container to the decontamination area, where cleaning should be completed immediately.^{23,24}
 5. Disposable cannulas and tubing should be used whenever possible, and they should be discarded after each use. These devices are sold without DFU for cleaning, and thorough cleaning is difficult to achieve and to validate.²⁵
 6. Devices labeled for single use only should not be reused; single-use devices do not include instructions for reuse or reprocessing. The FDA actively regulates third-party and hospital re-processors of single-use devices according to FDA guidance.³²
 7. To avoid contamination with bioburden and cleaning chemicals, intraocular instruments should be cleaned separately from non-ophthalmologic surgical instruments.
 8. The importance of enzymatic detergents for the cleaning of soiled intraocular instruments has not been established. Inappropriate use and incomplete rinsing of enzymatic detergents have been associated with outbreaks of TASS.¹⁶ If the DFU does not prohibit the use of a detergent and if a detergent is used
 - a. Care should be taken to ensure instructions for proper dilution, outdate, and disposal are followed. The cleaning solution should be mixed with measured amounts of water and detergent (ie, not mixed with estimated volumes), according to the detergent's DFU.^{23,24,28}
 - b. Following cleaning with detergents, with or without the use of an ultrasonic cleaner, instruments should be thoroughly rinsed with copious volumes of water to ensure removal of all detergent. If rinse volumes are specified by the detergent manufacturer's DFU or by the equipment manufacturer's DFU, they should be considered minimum volumes. Use of tap water for rinsing and for removal of detergent should be compatible with the manufacturer's DFU for the detergent and for the equipment. The final rinse should be with sterile distilled or sterile deionized water.^{25,29,30}
 9. If an ultrasonic cleaner is used
 - a. Ensure that gross soil has been removed prior to placement in the ultrasonic cleaner.
 - b. Check the manufacturer's DFU of instruments to identify instruments that should not be subjected to ultrasonic cleaning.
 - c. An ultrasonic unit designated for cleaning of medical instruments should be used.⁴
 - d. Validation of functioning, degassing, and preventive maintenance should be performed as recommended in the ultrasonic cleaner's DFU.^{23,24}
 - e. Ultrasonic machines must be emptied, cleaned, disinfected, rinsed, and dried at least daily and preferably after each use.^{17,18,33} Unless specified otherwise by the manufacturer, cleaning should be performed with an EPA-registered, facility-approved disinfectant and followed by sterile or tap water rinse sufficient to fully remove the cleaning agent. If not contraindicated by the ultrasonic cleaner's manufacturer, final rinse with 70% to 90% ethyl or isopropyl alcohol is recommended when feasible and unassociated with risk for fire. The machine should be dried completely with a lint freecloth.^{34,36}
 - f. Refilling should occur immediately prior to use.
 10. Manual cleaning processes
 - a. Brushes should be designed for cleaning medical instruments.
 - b. Cleaning tools such as syringes and brushes should be discarded after each use. If brushes are reused, they should be designed for reuse and they should be cleaned and high-level disinfected or sterilized, preferably after each use, or at least once daily.^{24,34}
 - c. Cleaning solutions should be discarded after each use.²⁴

- d. When flushing is used as part of a cleaning technique, the effluent should be discharged into a sink or separate basin so the fluid is not reused. Discharge of the effluent should be completed to minimize splash and aerosolization.
11. Rinsing
- Follow the manufacturer's DFU for selecting the appropriate type of rinse water for equipment.
 - Unless otherwise specified by the manufacturer's DFU, sterile distilled or sterile deionized water should be used for the final rinse of instruments.²⁵
 - Rinsing should provide flow of water through and/or over instruments, with effluent discarded as it is used, so only debris-free water is used for rinsing.
 - Agitation in a basin of water should not be used as a final rinse.
12. Following thorough rinsing, instruments with lumens should be dried with forced or compressed air.
- Compressed air should be filtered and free of oil and water.
 - Instruments with lumens should be fully dried.²³
13. Specific instruments: phacoemulsifier handpiece, irrigator/aspirator, irrigator/aspirator tips, and inserters
- Flush phacoemulsifier handpiece with balanced saline solution prior to removing from the operative field.
 - Wipe each instrument with a lint-free cloth and place immediately in a bath of sterile water. Remove from the operative field and remove from sites that maintain instruments needed for completion of the surgical procedure, in strict accordance with the manufacturer's DFU for each piece of equipment. To avoid introduction of water or reintroduction of gross soil to the operative field, the sterile water bath should be clearly separated from the operative field.²³
 - Clean and flush each item in accordance with the manufacturer's DFU and verify removal of all debris inclusive of OVD.
 - Inspect irrigator/aspirator tips, preferably under magnification, before sterilization.^{23,25}
14. If reusable woven materials are used for draping the sterile field, to absorb condensate in steam-sterilized instrument trays or to wipe instruments, they should be laundered and rinsed thoroughly between each use to eliminate surgical compounds, debris, and cleaning agents.
- Inadequate rinsing of high pH detergents used in institutional laundering can leave chemical residues that could be transferred to intraocular instruments.³⁰ Laundry procedures should be reviewed and monitored to ensure delivery of residue-free, reused woven materials; otherwise disposable, chemical, and lint-free materials should be used.
 - All woven materials used in intraocular surgery or instrument management should be lint free.
15. Cleanliness and integrity of instruments should be verified.^{23,24}
- Instruments should be visually inspected for debris and damage, preferably under magnification, immediately after cleaning and before packaging for sterilization to ensure removal of visible debris.^{24,25,30,37}
 - Additional or repeated cleaning and rinsing steps may be required on a case-by-case basis to ensure removal of all debris and OVD.
 - Surgeons should examine instruments under the microscope prior to each use and reject any instrument that shows signs of residual debris or defects.³⁸
16. Sterilization
- The method for sterilizing intraocular surgical instruments should be in accordance with the DFU of the instruments and with the DFU of the sterilizer manufacturer.^{22,24}
 - Steam sterilization should be completed in accordance with published guidelines.^{22,24}
 - Glutaraldehyde is not recommended for sterilizing intraocular instruments because of the toxicity of glutaraldehyde residues resulting from inadequate rinsing or contamination during post-sterilization handling. Other low temperature methods of sterilization should not be used unless the ophthalmic instrument manufacturer and the sterilizer manufacturer have validated the method for the specific instruments with respect to efficacy of sterilization, potential ocular toxicity (eg, from oxidation of metals), and instrument functionality.¹⁹

- d. Verification of sterilizer function should be completed at least weekly, preferably daily, in accordance with the sterilizer manufacturer's instructions for use and with published guidelines, and documented in the facility log.^{22,24}
 - e. Measures should be taken to ensure that preventive maintenance, cleaning, and inspection of sterilizers are performed on a scheduled basis, according to the sterilizer manufacturer's written instructions.^{22,24} All preventive maintenance should be documented.
 - f. Maintenance of boilers, of the water filtration systems, and of the quality of water supplying the steam-sterilizing system should be verified at least yearly. Healthcare organizations may find consultation with companies specializing in boiler maintenance and water quality helpful.^{20,22,24}
17. Administrative controls should be implemented.
- a. Policies and procedures regarding cleaning and sterilizing intraocular surgical instruments should be written, reviewed periodically (at least annually), and kept readily available within the practice setting.^{22,23}
 - iv. Undergo competency validations by direct observation of performance, using a competency checklist to ensure uniform evaluation of all personnel.^{22,23}
 - d. Records of instrument use, of medication use, and of sterilization should be maintained in accordance with facility policy.^{22,24,25} Complete and detailed records will aid in the investigation of any occurrence of TASS.
 - e. A surveillance system for detecting TASS should be implemented. Cases of TASS should prompt re-evaluation of cleaning and sterilization procedures.
- b. A sufficient number of instrument sets, phaco emulsifier handpieces, irrigator/aspirators, and inserters should be purchased to allow adequate time for cleaning and sterilization between procedures.
 - c. Personnel involved in handling and cleaning and/or sterilizing intraocular surgical instruments should
 - i. Be educated about TASS and its causes at hire and updated regularly thereafter.²⁵
 - ii. Receive initial education, training, and validation of competency in the cleaning, inspection, preparation, packaging, sterilization, storage, and distribution of all intraocular surgical instruments. Education, training and validation of competency should be updated at least annually and prior to introduction of any new devices or procedures.^{22,23}
 - iii. Be educated and trained in cleaning and sterilization procedures as well as related tasks (eg, equipment operation, preventive maintenance) via a formal, standardized training program administered by qualified personnel.²²

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APPENDIX

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