

Revisions to the Inspection Program Requirements for Existing premises/5-year scheduled inspection are indicated in the table below as follows:

~~Deletion~~

Addition

<b>1.0 Physical Requirements</b>
<b>1.1 General</b>
<del>1.1.1 Site complies with all applicable building codes including fire safety requirements.</del>
<del>1.1.3.1 Access for persons with disabilities complies with provincial legislation (<i>Accessibility for Ontarians with Disabilities Act</i>).</del>
<del>1.2.1.1 Temperature and ventilation ensures staff and patient comfort.</del>
1.1.1-5.3 The following areas are functionally separate, allowing adequate space to ensure patient safety, and that emergency protocols and infection control standards can be met. This may include separate, dedicated rooms, or designated areas, depending on the available space. <ul style="list-style-type: none"> <li>• administration and patient-waiting area/room</li> <li>• <del>procedure</del> IVIT administering area/room</li> <li>• clean utility area/room</li> <li>• non-sterile storage area/room</li> <li>• compounding area/room</li> <li>• recovery area/room.</li> </ul>
1.1.2 Layout of all rooms/areas facilitates safe, comfortable patient care and patient flow.
1.1.3 Premises is neat, comfortable, clean, and free of clutter.
1.1.4 Openings to the outside are effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means.
1.1.5 The appropriate compounding designated area/room containing the laminar air flow hood is in <del>(separate room or a low and controlled</del> traffic area with controlled, limited access).
1.1.6 A sink is readily available in the premises for staff use.
1.1.7 IV drugs/substances are located adjacent to the compounding area, in a low traffic area with controlled, limited access.
1.1.8 Electrical outlets are available. No overloaded wall-plugs or overloaded extension cords are in use.
<b>1.2 Infection Control</b>
1.2.1 Floors, and walls, chairs, examination tables, patient contact surfaces, etc can be cleaned to meet infection control requirements (eg surfaces are smooth and washable).
1.2.2 <del>In premise a</del> Access to hand-washing facilities and with proper towel disposal available to patients and all staff.
1.2.3 Alcohol-based hand cleaner is readily available throughout the premises for staff and patients.
1.2.4 Tissue boxes are available throughout the premises for staff and patients.
1.2.5 Disposable masks are readily available for patients. <del>along with signage for proper use.</del>
1.2.6 Infection control signs are prominently posted. <del>at the entry and at the reception desk.</del>
1.2.7 Infection control signage includes how to prevent the spread of infections (e.g. use of alcohol-based hand sanitizer, use of masks, etc).
1.2.8 A telephone, in person or online infectious disease screening protocol <del>has been developed and is</del> consistently implemented for use when communicating with patients and scheduling appointments.
1.2.9 Garbage cans are readily available throughout the premises for staff and patients.
1.2.10 Reception staff are protected from possible exposure (e.g. use of personal protective equipment, <del>can</del> maintaining a safe distance (approximately 1 meter) from patients, or protective barriers are in place).
1.2.11 A patient segregation area is available, when needed.
1.2.12 Clean toy and soiled toy bins are used, where applicable.
<b>1.3 Emergency Measures</b>

1.3.1 Hallways, stairways, and elevators ( <del>where applicable</del> ) are sufficiently wide to allow emergency evacuation of a patient by emergency personnel and their equipment.
1.3.2 The premise is equipped with a fire/ <del>smoke</del> alarms, smoke detectors and/or a sprinkler system. <del>that conforms to local fire codes and fire safety training.</del>
1.3.3 Fire exits are clearly marked, and evacuation maps are <del>prominently displayed</del> <del>located</del> in all patient areas.
1.3.4 Notices are posted and readily visible in common areas indicating an AED is on site.
1.3.5 The AED is fully stocked, the AED pads are not expired, the battery is fully charged, and the unit is fully operational.
1.3.6 There is emergency lighting in all patient <del>care</del> areas. Emergency lighting may include but is not limited to a permanently installed emergency system or battery powered portable devices.
1.3.7 Emergency procedures are <del>clearly displayed.</del> readily available for staff to use in the event of a patient-related emergency.
1.3.8 A crash cart is immediately available and fully stocked.
<b>2.0 Equipment and Supplies</b>
<b>2.1 General</b>
2.1.1 All electrical devices <del>are certified by CSA or licensed for use in Canada</del> meet Canadian electrical safety requirements and contain certification marks, such as CSA, cUL or cETL.
2.1.2 Sharps/biohazard containers are <del>readily available to staff</del> puncture-resistant, tamper-resistant, leak-proof with a clearly identifiable biological hazard label.
2.1.3 Sharps/biohazard containers are <del>readily available to staff</del> easily accessible in every “point of use” area and mounted out of the reach of children.
2.1.4 A laminar airflow hood is in place for premises where compounding for IVIT is conducted.
2.1.5 Appropriate personal protective equipment (PPE) is available for procedures where applicable.
2.1.6 Spill kit is readily available to clean gross spills of blood.
<b>2.2 Maintenance and Cleaning</b>
2.2.1 Laminar air flow hood has been certified as recommended by manufacturer.
2.2.2 Equipment used for administering IVIT is maintained and inspected regularly for functionality and is recorded in the applicable log.
2.2.3 Equipment used for compounding IVIT is maintained and inspected regularly for functionality and is recorded in the applicable log.
2.2.4 Approved and appropriate cleaning and disinfecting products are available for cleaning and disinfecting patient surfaces.
2.2.5 Approved and appropriate cleaning and disinfecting products are available for cleaning and disinfecting equipment and instruments.
2.2.6 Cleaning and disinfecting of patient surfaces, equipment, and instruments is recorded in a cleaning log.
<b>2.3 Items Required on the Crash Cart</b>
<ol style="list-style-type: none"> <li>1. Alcohol</li> <li>2. Angiocatheters</li> <li>3. Atropine i.v.</li> <li>4. Calcium chloride and/or Calcium gluconate and/or Calcium glycerophosphate i.v.</li> <li>5. Dextrose 5% (D5W) and 50% i.v.</li> <li>6. Diphenhydramine hydrochloride i.v., i.m.</li> <li>7. Epinephrine hydrochloride i.m.</li> <li>8. Ipratropium bromide</li> <li>9. IV tubing and administration sets</li> <li>10. Magnesium chloride and/or Magnesium sulfate i.v.</li> <li>11. Micropore tape</li> <li>12. Nitroglycerin</li> <li>13. Non-latex gloves</li> <li>14. Non-latex tourniquets</li> <li>15. Oxygen tank with regulator 0-10 L/min with mask or nasal canula</li> </ol>

16. Pocket mask for cardiopulmonary resuscitation
17. Resuscitation bag with O<sub>2</sub> attachment
18. Safety engineered needles
19. Salbutamol
20. Saline bags
21. Smelling salts (amyl nitrate) or essential oil (peppermint)
22. Syringes

#### **2.4 Equipment and Supplies ~~not on Crash Cart but~~ Readily Available**

1. Arm board ~~or other support (e.g. pillow with disposable cover)~~
2. Automated External Defibrillator (AED)
3. Basic dressing supplies
4. Cold compresses, hot packs
5. Cotton balls
6. Gauze and bandages
7. Lidocaine (topical)
8. Natural anxiolytic
9. Non-latex blood pressure cuff
10. Pulse oximeter
11. Scissors
12. Snacks (crackers, fruit juices)
13. Stethoscope
14. Thermometer
15. Watch (if no ~~wall~~ clock with second-hand present in the room)

#### **3.0 Drugs and Substances Storage and Inventory**

3.1 Only drugs/substances listed on Tables 2 and 5 of the *General Regulation* are stocked for compounding for and/or administering by IVIT.

3.2 Drugs/substances not listed on Tables 2 and 5 of the *General Regulation* ~~may be~~ are stocked ~~if they are being~~ for compounding for and/or administering ~~through~~ by IVIT **only** when a delegation is in place.

~~4.1.1.5 Only drugs/substances approved for use by the College of Naturopaths of Ontario for IV administration are used.~~

3.3 An IVIT ~~general~~ drug/substance inventory record, ~~which~~ includes expiration dates and lot numbers, is maintained and up to date.

3.4 ~~When applicable,~~ IVIT drugs/substances are labelled to indicate the date they were initially punctured ~~seal was broken~~.

3.5 Once a single-use vial has been punctured it must be used within 12 hours.

3.6 Once a multi-dose vial has been punctured, it is not used beyond the manufacturer's beyond-use date or 28 days, whichever is shorter.

3.7 IVIT drugs/substances are stored according to the manufacturer's recommendations, eg room temperature, refrigerated, away from light.

3.8 IVIT drugs/substances are organized for easy access in ~~appropriately~~ labeled bins, cupboards and shelves, including those in the refrigerator.

3.9 IVIT drugs/substances requiring refrigeration are ~~properly~~ stored in a ~~dedicated~~ refrigerator ~~dedicated to injectable drugs/substances only~~. ~~with the temperature check regularly (eg. use of a thermometer that registers maximum and minimum temperatures and has a visual readout externally).~~

3.10 ~~Drugs/substances requiring refrigeration are properly stored in a dedicated~~ The refrigerator used for IVIT drugs/substances is at ~~with~~ the correct temperature (2-8 °C) ~~check regularly (eg. use of~~ and monitored with a thermometer that ~~registers records~~ maximum and minimum temperatures and ~~has~~ includes an external visual readout ~~externally~~).

3.11 A refrigerator temperature log is maintained and up to date.

3.12 Expired or contaminated drugs, substances and equipment are labelled and stored <b>separately from current products</b> , to ensure they are not used <del>and are discarded appropriately</del> before being properly discarded. (May use the Ontario Medications Return Program)
<del>4.1.1.6 Drugs/substances appropriate for paediatric administration are available if applicable.</del>
<del>4.1.1.7 Drugs/substances are labeled in accordance with CONO's General Regulation and Standard of Practice for Compounding.</del>
<b>4.0 Policies and Procedures Manual</b>
<b>4.1 Administrative</b>
4.1.1 Staff person(s) responsible for developing and maintaining the Policy and Procedure Manual <b>is determined</b> .
4.1.2 Organizational chart
4.1.3 Scope and limitations of the services provided at the premise.
4.1.4 Descriptions for all premises staff <b>who are involved with patients receiving IVIT</b> that define the scope <b>responsibilities</b> and limitations <b>of their duties and responsibilities for patient care</b> .
<del>11.2.2 Responsibilities for supervising staff.</del>
<b>4.2 Operational Procedures</b>
4.2.1 Storage, handling, and disposal of combustible and volatile materials.
4.2.2 IVIT drugs and substances handling and inventory.
4.2.3 Cold chain management - <b>storage and handling of drugs and substances requiring a controlled cold temperature</b> .
4.2.4 <del>Routine</del> <b>Appropriately scheduled</b> maintenance and/or calibration of IVIT equipment <b>and updating the maintenance log</b> .
4.2.5 <del>The following</del> Documentation for all equipment used <b>when for administering and compounding for IVIT is available included</b> : <ul style="list-style-type: none"> <li>• equipment operating manuals, <b>where applicable</b>,</li> <li>• equipment maintenance contracts, where applicable,</li> <li>• maintenance log,</li> <li>• <b>inventory list</b>.</li> </ul>
<del>1.3.2.3 The following documentation for all equipment used for <u>compounding</u> IVIT is available:</del> <ul style="list-style-type: none"> <li>• <del>equipment operating manuals</del></li> <li>• <del>equipment maintenance contracts, where applicable</del></li> </ul> <b>maintenance log.</b>
<del>4.2.7 Patient booking system.</del>
<del>4.2.8 Obtaining patient informed consent.</del>
4.2.6 Patient preparation for IVIT procedures.
4.2.7 Response to latex allergies <b>including accidental exposure in a latex-free clinic</b> .
4.2.8 <b>Handling and disposal of biomedical and non-biomedical waste. and garbage disposal.</b>
<b>4.3 Type 1 and Type 2 Occurrences</b>
4.3.1 <b>Ensures</b> All staff are aware of <del>the requirements of when and who to report</del> <b>what</b> Type 1 and Type 2 occurrences <b>are to</b> .
4.3.2 <b>Ensures</b> All staff are aware of <del>the possible occurrences that can happen and how staff are to ensure they are reported to the College and the designated member and recorded in the patient file</del> <b>when and whom they must report Type 1 and Type 2 occurrences to</b> .
4.3.3 <b>Establishes</b> How Type 1 and Type 2 occurrences are responded to. <del>including the criteria to determine if emergency services are required. In an occurrence where emergency services are not required ensure the necessary procedures to provide patient care are included.</del>
4.3.4 Record keeping for all Type 1 Occurrence, Type 2 Occurrence Tracking (i.e. filed in the patient file as well as in a master file), and Type 2 Occurrence Annual reports.
4.3.5 Requirement to report a death occurring within the premises <del>should also be reported</del> to the coroner.
<b>4.4 Emergency Response and <del>Safety Precautions</del> Management</b>

4.4.1 A risk analysis for the premises, <del>of the practice is conducted, and documented, based on, at a minimum, the following criteria</del> as outlined in the <i>Standard of Practice for Emergency Preparedness</i> , that includes: <ul style="list-style-type: none"> <li>• volume of patients,</li> <li>• volume of high-risk patients,</li> <li>• proximity to a hospital,</li> <li>• proximity to an emergency room,</li> <li>• acuity of illness of patients, and</li> <li>• access to emergency services.</li> </ul>
4.4.2 Management of patient emergencies.
4.4.3 Management of an emergency due to fire.
4.4.4 Management of an emergency due to a power failure.
4.4.5 Management of other emergencies requiring immediate evacuation.
4.4.6 Emergency situations that need 911 to be called.
4.4.7 How and when to summon additional staff urgently within the premise.
4.4.8 How a patient in urgent need of transfer is to be transferred to hospital <del>by an appropriate transportation service</del> (in most cases this would be by ambulance).
4.4.9 How the ND most responsible for the patient <del>ensures that sends</del> essential <del>medical</del> information <del>is sent</del> with the patient.
4.4.10 How to ensure a regulated health professional <del>staff member should</del> accompanies the patient during the transfer.
<del>11.5.4 If the ND most responsible for the patient is not accompanying the patient, he/she must contact the receiving physician/premises immediately, by phone or in person.</del>
<del>11.5.5 The ND most responsible for the patient must complete a report.</del>
<b>4.5 Infection Control</b>
4.5.1 Infection control protocols, including cleaning protocols, that <del>Premise</del> adhere to <del>and maintains</del> <del>documentation for</del> accepted standards of infection control practices.
4.5.2 <del>A procedure is in place</del> Protocol to decontaminate gross blood spills.
4.5.3 Protocols for cleaning the laminar air flow hood.
4.5.4 Protocols for hand hygiene when performing IVIT procedures.
4.5.5 A telephone, in person or online infectious disease screening protocol used when communicating with patients and scheduling appointments.
4.5.6 When and how staff are to use personal protective equipment to protect themselves and others.
4.5.7 <del>Referral for post-exposure prophylaxis is recommended for</del> Process to ensure all staff who are exposed to <del>with</del> blood and/or body fluids <del>exposure</del> are referred for post-exposure prophylaxis.
<b>4.6 Training</b>
4.6.1 Processes to ensure completion of staff training for: <ul style="list-style-type: none"> <li>• infection prevention and control,</li> <li>• proper use of personal protective equipment (PPE),</li> <li>• proper hand hygiene,</li> <li>• emergency procedures,</li> <li>• waste disposal,</li> <li>• inventory handling and storage,</li> <li>• handling gross blood spills,</li> <li>• cleaning equipment and patient surfaces, and,</li> <li>• other areas as determined by the premises.</li> </ul>
<b>4.7 Quality Management Program</b>
Processes regarding the Quality Management Program include:
4.7.1 Formation of a Quality Management Committee and the staff members, who are involved with patients receiving IVIT, comprising the committee.
4.7.2 Frequency and reasons for Quality Management Committee meetings.

4.7.3 Staff review of the Policies and Procedures Manual, at least annually.
4.7.4 <del>Process to review individual ND</del> Performance review of naturopath(s) who perform IVIT procedures. <del>(procedure selection, patient outcomes, occurrences, etc.)</del>
4.7.5 Review of staff who are involved in delegated procedures to ensure all requirements outlined in the <i>Standard of Practice for Delegation</i> and Part III of the <i>General Regulation</i> are met.
4.7.6 <del>Process to review the</del> Performance review of non-medical staff involved in any of the premise's IVIT related processes and procedures.
4.7.7 Reviewing that staff are aware of and trained in the premise's emergency procedures, including use of the AED.
4.7.8 Reviewing that staff are aware of and consistently use the telephone, in person and online infectious disease screening protocol when communicating with patients and scheduling appointments.
4.7.9 Reviewing that staff are aware of how and when to use personal protective equipment.
4.7.10 Reviewing that staff are aware of procedures to follow in the event of exposure to blood or body fluids.
4.7.11 Monitoring and evaluating the quality of patient care provided.
4.7.12 Tracking and reviewing patient outcomes.
4.7.13 Developing and implementing methods to improve patient care.
4.7.14 Identifying and correcting deficiencies in the premise's policies and procedures.
4.7.15 Reviewing all Type 1 and Type 2 reporting and record keeping requirements.
4.7.16 <del>Process to</del> Reviewing all Type 1 and Type 2 occurrences that occurred at the premises, <del>including potential remedial actions that may be taken</del> and developing policies and procedures to reduce the risk of <del>prevent</del> future occurrences <del>and mitigate harm to patients</del> .
4.7.17 <del>Process to randomly</del> Selecting, at least annually, and reviewing 5-10 patient records to assess: <ul style="list-style-type: none"> <li>• quality of care to patients,</li> <li>• completeness and accuracy of entries,</li> <li>• documentation of informed consent,</li> <li>• appropriateness of treatment,</li> <li>• follow-up to abnormal laboratory test results, and</li> <li>• <del>to ensure records</del> adherence to the <i>Standard of Practice for Record Keeping</i>.</li> </ul>
4.7.18 Monitoring adherence to infection control practices pertinent to IVIT.
4.7.19 Monitoring proper cleaning procedures for patient surfaces and IVIT equipment.
4.7.20 Monitoring maintenance of IVIT and emergency equipment.
4.7.21 Monitoring the drug and substance inventory and storage (including cold chain management).
4.7.22 Monitoring labelling and disposal of expired drugs, substances, and equipment.
4.7.23 Monitoring use of logs for inventory, cleaning, and maintenance.
4.7.24 Reviewing proper handling and disposal of all biomedical and non-biomedical waste.
<del>11.7.4 Process to review compliance with all policies and procedures in the manual.</del>
<b>4.8 Delegation</b>
4.8.1 <del>Delegating controlled acts.</del> Processes to ensure the criteria for <u>making</u> a delegation as outlined in the <i>Standard of Practice for Delegation</i> and Part III of the <i>General Regulation</i> are met.
4.8.2 How to meet the criteria for <u>accepting</u> a delegation as outlined in the <i>Standard of Practice for Delegation</i> and Part III of the <i>General Regulation</i> are met.
<b>4.9 Miscellaneous</b>
4.9.1 All forms used at the premises (intake, IV treatment, consent, Type 1 occurrence report, Type 2 occurrence tracking).
4.9.2 Templates of all logs including inventory, maintenance, cleaning, refrigerator temperature, etc
4.9.3 Any external policies, as deemed necessary by each individual premises.
<b>5.1 Compounding IV Bags</b>
5.1.1 Laminar air flow hood (LAFH) has been turned on at least 30 minutes prior to use.
5.1.2 LAFH is cleaned with sterile 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes before and after use.

5.1.3 <del>It is</del> Verify <del>that the</del> proper IVIT <del>prescription</del> formula (whether compounded on site or by a compounding pharmacy) <del>is being prepared for</del> and the intended patient.
5.1.4 Calculate osmolarity <del>before compounding</del> .
<del>7.1.5 Proper infection controls and prevention of contamination procedures are followed when working under the laminar airflow hood.</del>
5.1.5 <del>Bottles are</del> All needed bags, vials and containers are collected and checked for: <ul style="list-style-type: none"> <li>• beyond use <del>expiry</del> date, to ensure it is current,</li> <li>• <del>proper</del> concentration,</li> <li>• leaks,</li> <li>• defects that could compromise sterility, and</li> <li>• <del>contamination</del>, abnormal appearance – cloudiness, colour, precipitate.</li> </ul>
5.1.6 <del>All packages are checked to</del> All needed compounding equipment is collected, checked for the expiration date where applicable and ensured it is new and not previously opened.
5.1.7 The person performing the compounding <del>under the laminar airflow hood washes their hands</del> follows proper hand hygiene <del>with a suitable antimicrobial</del> at the beginning, and <del>when re-entering the aseptic preparation area</del> before donning gloves to compound under the laminar air flow hood in accordance with <i>PIDAC – Infection Prevention and Control for Clinical Office Practice</i> .
5.1.8 The person performing the compounding dons a <del>Personnel use protective equipment of</del> mask, gown, and gloves at a minimum; (hair, shoe, and beard (when applicable) covers are optional).
5.1.9 All bottles, vials, containers, and equipment necessary for compounding <del>the preparation</del> are disinfected with 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes as they are placed under the LAFH prior to <del>commencing the</del> compounding. <del>are wiped down with alcohol or disinfectant before being brought into the laminar airflow hood</del>
5.1.10 Sterile items that are in sealed containers designed to keep them sterile are removed from the covering as they are introduced into the LAFH without being wiped.
5.1.11 All objects are suitably place in the LAFH to provide good airflow with minimal obstruction.
5.1.12 <del>Bottles are swabbed with alcohol and left for 30 seconds before puncturing.</del> Vial stoppers, ampule necks and intravenous bag septa are wiped with 70% isopropyl alcohol and allowed to dry before entering or puncturing stoppers and septa, or breaking the necks of ampules.
5.1.13 Proper drawing technique is used (e.g. calcium gluconate is added last or a new needle is used, 45° angle with bevel up entry into rubber stoppers).
5.1.14 All drugs and substances are added to the iv bag and mixed well. <del>Finished product is inspected for visible precipitate.</del>
5.1.15 Once compounded, the iv bag is checked for leaks, <del>contamination</del> , and abnormal appearance - cloudiness, colour, and precipitate.
5.1.16 <del>Direct contact between a sterile product and a non-sterile product is avoided.</del> Gloved hands are disinfected with 70% isopropyl alcohol before re-introduction into the LAFH or after gloves have been in contact with a non-sterile surface during the compounding procedure.
5.1.17 All sharps are disposed of in a puncture-resistant, tamper-resistant, leak-proof sharps container.
5.1.18 All materials are disposed of properly.
5.1.19 The iv bag label <del>used</del> is disposed of in a secure manner, such that any identifying information is destroyed or unreadable.
<b>5.2 Labelling</b>
5.2.1 The name of the patient for whom the bag was compounded, <del>or an identification number.</del> <del>if applicable</del>
5.2.2 The <del>member</del> -Registrant's name and title, <del>address, and telephone number.</del>
5.2.3 The name <del>of the person who compounded the iv bag, and the</del> address and telephone number of the place where the bag was compounded <del>if different from above.</del>
5.2.4 <del>identification</del> The names and strength of the drugs, substances and any other ingredients used in the compounding, <del>the names and strength</del> and the manufacturer if available.
5.2.5 The amount or percentage of each of the drugs, substance and any other ingredients used to make the compounded product and the <del>total</del> quantity of the compounded product in the container.

5.2.6 The date that the <b>iv bag compounded drug</b> was: <ul style="list-style-type: none"> <li>• prepared, <del>and the date that the compounded drug was</del></li> <li>• administered to the patient , and</li> <li>• the expiry date. <del>of the iv bag, even if the bag is to be used on the same day it is compounded,</del></li> </ul>
5.2.7 The directions for storage of the iv bag.
5.2.8 <b>The directions for</b> use of the iv bag, including <del>its</del> dose, frequency, route of administration and any special instructions.
5.2.9 Any cautionary information about the drug or substance.
<b>6.0 Observed IVIT Treatment</b>
<b>6.1 Pre-treatment Preparation</b>
6.1.1 The patient is <del>re-assessed including a review of</del> questioned regarding any change in their symptoms, medications, <b>and</b> supplements; <b>consideration has been given to possible new contraindications and if additional diagnostic tests are needed.</b>
6.1.2 Informed consent is obtained, and all the patient's questions are answered.
6.1.3 <b>The patient is verified for IVIT treatment being administered.</b>
6.1.4 <del>Collect IV</del> <b>Equipment needed to administer IVIT is collected:</b> <ul style="list-style-type: none"> <li>• administration set</li> <li>• alcohol</li> <li>• cotton</li> <li>• gloves</li> <li>• safety engineered needles</li> <li>• tape</li> <li>• tourniquet.</li> </ul>
6.1.5 Collect IV bags and inspect for leaks, <del>and</del> cloudiness, <del>and abnormal appearance</del> colour, and precipitate.
6.1.6 Patient is questioned regarding: <ul style="list-style-type: none"> <li>• use of restroom, <b>and</b></li> <li>• <del>fears/anxiety around treatment</del></li> <li>• <del>history of fainting due to needles</del></li> <li>• <b>the last time they have eaten.</b></li> </ul>
6.1.7 <del>Ensure infection control procedures are followed—e.g. wash hands, establish clean field.</del> <b>The person administering the IVIT washes their hands and dons gloves.</b>
6.1.8 <del>Ensure infection control procedures are followed—e.g. wash hands, establish</del> <b>Clean and dirty fields are established.</b>
6.1.9 Appropriate <del>IV equipment is</del> <b>items are</b> placed in <b>the</b> clean field.
6.1.10 Pre-treatment vital signs are taken: <ul style="list-style-type: none"> <li>• blood pressure</li> <li>• heart rate</li> <li>• respiratory rate or pulse oximeter reading</li> <li>• temperature.</li> </ul>
6.1.11 <b>All relevant pre-treatment information is entered in the patient chart.</b>
<del>8.1.10 Administration set is properly set up</del>
6.1.12 <b>The administration set is attached to the IV bag and the line is flushed.</b>
6.1.13 <b>The drip chamber is set to half full.</b>
<b>6.2 Delivery and Termination of IVIT</b>
<del>6.2.1 Patient is properly positioned and prepared for injection.</del>
6.2.1 <b>The patient's arm is properly positioned and supported.</b>
6.2.2 <b>The tourniquet is applied.</b>
6.2.3 <b>The appropriate injection site is selected.</b>
6.2.4 <b>The injection site is swabbed with 70% isopropyl alcohol.</b>
<del>8.2.2 The IV is inserted and drip started.</del>



6.2.5 The angiocatheter or butterfly needle is inserted.
6.2.6 The angiocatheter/needle is checked for a back flow of blood (flashback).
6.2.7 The tourniquet is released.
6.2.8 The administration line is attached.
6.2.9 The angiocatheter/needle is taped and secured.
6.2.10 The IV drip is started and the drip rate set.
6.2.11 The insertion site is monitored during the treatment.
6.2.12 The patient's vital signs are monitored during treatment when indicated or for infusions that take longer than 30 minutes to administer: <ul style="list-style-type: none"> <li>• blood pressure</li> <li>• heart rate</li> <li>• respiratory rate or pulse oximeter reading</li> <li>• temperature, when indicated are recorded).</li> </ul>
<del>8.2.4 IV drip is terminated, and all materials are properly disposed of.</del>
6.2.13 Once the iv bag has been administered, the angiocatheter/ needle and tape are removed.
6.2.14 The angiocatheter/needle is checked to ensure it is intact and there is no breakage.
6.2.15 Pressure is applied with gauze or a cotton ball once the angiocatheter/ needle is removed.
6.2.16 A bandaid is applied or cotton ball taped down over the insertion site.
6.2.17 All waste is handled and disposed of properly.
6.2.18 All sharps are disposed of in a puncture-resistant, tamper-resistant, leak-proof sharps container.
6.2.19 The insertion site is observed post-treatment for redness, swelling or hematoma. Treatment is provided as needed.
6.2.20 Post-treatment vital signs are taken: <del>after treatment.</del> <ul style="list-style-type: none"> <li>• blood pressure</li> <li>• heart rate</li> <li>• respiratory rate or pulse oximeter reading</li> <li>• temperature, when indicated.</li> </ul>
6.2.21 Appropriate post-treatment instructions are given to the patient, including reporting to the ND any serious health events such as shock or convulsions, infections, allergic reactions, and adverse reactions. Also any unscheduled treatments as a result of the IV treatment, that may include visit to a hospital emergency department or another health care practitioner are to be reported.
6.2.22 All relevant information is entered on an IVIT-specific treatment form in the patient chart.
<del>8.2.8 Only qualified personnel deliver treatment in accordance with their knowledge, skill and judgment.</del>
<del>8.3.1 Universal precautions are followed.</del>
7.1 When administering IVIT, the following are used for only one patient: <ul style="list-style-type: none"> <li>• needles,</li> <li>• syringes,</li> <li>• <del>iv</del> bags of IV solution,</li> <li>• <del>medication,</del></li> <li>• administration tubing and connectors are never reused.</li> </ul>
7.2 Gloves are used for a single task and are never re-used.
7.3 Appropriate <del>additional precautions are applied as</del> personal protective equipment is used when necessary <del>re: to protect against</del> airborne, contact and droplet transmission. <del>-or contact precautions.</del>
<del>8.3.6 Staff wear appropriate personal protective equipment (PPE).</del>
7.4 Approved and appropriate cleaning and disinfectant products are <del>available for</del> used to clean and disinfect patient surfaces, <del>equipment, and instruments.</del>
7.5 Approved and appropriate cleaning and disinfectant products are <del>available for</del> used to clean and disinfect <del>patient surfaces,</del> equipment, and instruments.
7.6 The cleaning and disinfecting log is kept up to date.
<b>8.0 Quality Management</b>

<del>10.1.1 Documentation that a Quality Management Committee has been established and is comprised of all staff providing IVIT related patient care.</del>
8.1 The Quality Management Committee meets in accordance with the Policies and Procedures Manual.
8.2 <del>A process is in place to ensure that all</del> Staff reviews the Policies and Procedures Manual <del>on an</del> at least annually basis.
8.3 Naturopathic doctor(s) performance is reviewed as it relates to IVIT processes and procedures. <del>including patient selection to ensure appropriateness of treatment.</del>
8.4 Non-medical staff performance is reviewed as it relates to IVIT processes and procedures.
8.5 Reviews that staff who are involved in delegated procedures are aware of and have met all requirements outlined in the <i>Standard of Practice for Delegation</i> and Part III of the <i>General Regulation</i> are met.
8.6 Reviews that all staff are aware of and trained in the clinic's emergency procedures, including use of the AED.
8.7 Reviews that staff are aware of and consistently use the telephone, in person or online infectious disease screening protocol when communicating with patients and scheduling appointments.
8.8 Reviews that staff are aware of how and when to use personal protective equipment in order to protect themselves and others.
8.9 Reviews that staff are aware of procedures to follow in the event of exposure to blood or body fluids.
8.10 The quality of patient care provided is monitored and evaluated.
8.11 Patient outcomes are tracked and reviewed.
8.12 <del>evaluates</del> Methods to improve patient care are developed and implemented.
8.13 Deficiencies regarding policies and procedures are identified and corrected. <del>deficiencies within the premises</del>
<del>alerts the designated member to identify and resolve problems.</del>
8.14 Reviews that staff are familiar with Type 1 and Type 2 occurrences.
8.15 Reviews that staff have met the reporting requirements for Type 1 and Type 2 occurrences.
8.16 Reviews that staff have met the record keeping procedures for Type 1 and Type 2 occurrences that have happened.
8.17 <del>Complications and</del> Type 1 and Type 2 occurrences <del>are tracked and evaluated.</del> that have happened are reviewed and the procedures to reduce the risk of future occurrences are reviewed, developed, and implemented.
8.18 At least annually, a random selection of 5-10 patient records is reviewed to assess for: <ul style="list-style-type: none"> <li><del>• record completion and adherence to the <i>Standard of Practice for Record Keeping</i></del></li> <li>• documentation of informed consent</li> <li>• completeness and accuracy of entries</li> <li>• appropriateness of patient treatment</li> <li><del>• when required, reporting requirements are met in a timely manner</del></li> <li><del>• evaluation and follow-up of Type 1 and 2 occurrences</del></li> <li><del>• assessment of incidents requiring transfer to hospital</del></li> <li>• follow-up to abnormal laboratory test results.</li> </ul>
8.19 <del>Premise adheres to and maintains documentation for</del> Reviews that accepted standards of infection control practices pertinent to IVIT are being followed.
8.20 Reviews <del>of activities related to</del> that cleaning procedures are being followed and the cleaning log is properly maintained. <del>maintenance and storage of equipment.</del>
8.21 Reviews <del>of activities related to cleaning. Maintenance and storage of equipment.</del> that IVIT and emergency equipment is being maintained and the maintenance log is properly maintained.
8.22 Reviews <del>of activities related to monitoring</del> that drug and substance inventory is monitored, and the inventory log is properly maintained <del>and proper storage.</del>
8.23 Reviews <del>of activities related to monitoring</del> that drugs and substances are <del>inventory and</del> properly stored, and the refrigerator temperature log is properly maintained.
8.24 Reviews that expired drugs, substances and equipment are labelled and properly disposed of.
8.25 Reviews that biomedical and non-biomedical waste is being handled and disposed of properly

~~10.5.1 A process is in place for the reporting and documentation of Type 1 and 2 occurrences, incompetence or professional misconduct.~~

## 9.0 Patient Chart Requirements

### 9.1 Appointment Record

9.1.1 ~~Contains member's~~ Registrant's name, clinic name, address, and telephone number

9.1.2 ~~Contains the~~ Date and time of the appointment

9.1.3 ~~Contains the~~ Patient's name

9.1.4 ~~Indicates the~~ Duration of the appointment

9.2.1 Treating ~~Member's~~ Registrant's name, clinic name, address, and telephone number. ~~are recorded~~

9.2.2 Patient's name, ~~and~~ address, ~~and~~ telephone number. ~~are recorded on the receipt.~~

9.2.3 Date of service. ~~is recorded.~~

9.2.4 Fees for naturopathic consultation ~~are~~ (billed separately from all other fees).

9.2.5 Fees for supplements, injectables, etc are ~~listed~~ itemized and separately from the naturopathic consultation fee.

9.2.6 ~~Receipts are issued for all payments and~~ Copies of the receipts ~~are~~ provided to patient for all payments. ~~are maintained in the patient financial record.~~

9.2.7 ~~Financial record includes~~ Payment amount, method of payment and balance of the account

9.3.1 Patient's name, address, phone number, and date of birth. ~~are documented~~

9.3.2 ~~In the event that more than one health care practitioner is making entries in the patient chart, each practitioner is identified with his or her~~ Indication of who made each entry with a signature and registration number (when applicable), and the date the entry was made.

9.3.3 Patient name or patient number on each page.

9.3.4 All pages are in chronological order, consecutively numbered and dated.

9.3.5 All dates are recorded in a consistent format.

9.3.6 All entries are made in, at the least, either English or French.

9.3.7 All written records are legible.

9.3.8 All written entries are made in indelible ink.

9.3.9 No highlighter is used over writing.

9.3.10 Blank spaces are not left between entries.

~~6.3.12 All chart entries are recorded as soon as possible after the patient interactions.~~

9.3.11 A legend of abbreviations ~~or codes~~ is available when other than generally accepted medical abbreviations are used.

### 9.4 Informed Consent

9.4.1 Documentation of a discussion regarding consent indicating the patient understands the nature of the intervention, its expected benefits, the material risks and side effects, available reasonable alternatives, the likely consequences of not receiving the intervention, the associated costs, and the right to withdraw consent.

9.4.2 ~~Patient chart contains a signed informed consent form~~

Documentation in the form of a notation in the patient record or a consent form that is dated, signed, and witnessed.

9.4.3 Any modifications to the consent.

9.4.4 If consent is withdrawn, the reason(s) why and what was specifically withdrawn.

9.5.1 ~~The system provides~~ A visual display of the recorded information ~~can be provided.~~

9.5.2 The ~~system provides a means of accessing the~~ record of each patient ~~can be accessed~~ by the patient's name or other unique identifier.

9.5.3 The ~~system is capable of printing promptly the~~ recorded information ~~can be printed promptly~~ in chronological order for each patient.

9.5.4 ~~Confidentiality and privacy is maintained~~ Protections against unauthorized or inappropriate access are in place (e.g. password protection, encryption).

9.5.5 The system maintains an audit trail that:

- records the date and time of each entry for each patient,

<ul style="list-style-type: none"> <li>• preserves the original content of the record if changed or updated,</li> <li>• identifies the person making each entry or amendment, and</li> <li>• is capable of printing each patient record separately.</li> </ul>
9.6.1 The chief complaint(s) <del>is clearly stated the symptoms are adequately described, the duration of symptoms noted, and a functional inquiry is performed.</del>
9.6.2 Health, family and social history <del>is documented.</del>
9.6.3 Allergies <del>are identified and documented.</del>
9.6.4 Patient's <del>are screened for</del> history regarding exposure to and infection from methicillin resistant organisms (MROs). <del>and infectious diseases. This may include history taking and questioning of the patient.</del>
9.6.5 Assessment <del>includes</del> <del>is formulated from information from</del> one or more of the following: <ul style="list-style-type: none"> <li>• patient's health history,</li> <li>• physical exam with positive/negative findings documented,</li> <li>• lab tests and other diagnostic investigations that are clinically relevant.</li> </ul>
9.6.6 Blood tests performed in the office are only those listed in the General Regulation made under the Naturopathy Act (BTA Bioterrain Assessment, glucose, live blood cell analysis, haemoglobin A <sub>1c</sub> , mononuclear heterophile antibodies (monospot), free fatty acids, blood group – ABO and RhD).
9.6.7 Non-blood tests performed in the office are only those listed in Regulation #683 made under the Laboratory and Specimen Centre Collection Licencing Act (ascorbic acid/Vitamin C, BTA Bioterrain Assessment, human chorionic gonadotrophin, indican, Koenisberg, oxidative testing, routine urinalysis by dipstick, Sulkowich, rapid strep test and vaginal pH).
9.6.8 Laboratory tests ordered from an allowed laboratory are only those listed in Regulation 683 made under the <i>Laboratory and Specimen Centre Collection Licencing Act</i> .
9.6.9 Review of medications, remedies, and supplements. <del>is documented</del>
9.6.10 An assessment of the information collected and a diagnosis. <del>are documented</del>
9.6.11 <del>The</del> Proposed treatment plan. <del>is fully documented</del>
9.6.12 Name, strength, dosage, frequency, and method of administration for all drugs and substances included in the treatment plan.
9.6.13 Relevant communications with or about the patient. <del>are documented</del>
9.6.14 <del>The particulars of any</del> Relevant referral information, where applicable. <del>made is documented</del>
<del>6.5.13 Prior to the procedure the IVIT protocol along with risks, benefits, alternatives, potential complications and side effects, and costs were discussed with the patient/substitute decision maker and documented</del>
9.6.15 Relevant subjective and objective information obtained during re-assessments. <del>is documented</del>
9.6.16 Amendments to a written chart is initialled, dated and indicates what change was made.
9.6.17 Amendments are <del>only</del> made in the form of additions and not erasures or overwriting.
<del>9.6.18 A patient chart is never re-written</del>
9.7.1 <del>Whether or not the patient has</del> fears/anxiety around IVIT treatment
9.7.2 <del>Whether or not the patient has a</del> history of fainting due to needles
9.7.3 An IVIT specific form containing the following information:
9.7.3.1 Name and strength of all drugs/substances administered.
9.7.3.2 Formula of iv bag
9.7.3.3 Dosage and frequency.
9.7.3.4 Date of administration.
<del>6.7.4 Method of administration</del>
9.7.3.5 infusion site
<del>butterfly size</del>
9.7.3.6 catheter size
9.7.3.7 osmolarity
9.7.3.8 start time
9.7.3.9 end time
9.7.3.10 drip rate
9.7.3.11 vital sign (blood pressure, heart rate, respiratory rate or pulse oximeter reading, and temperature

when applicable) before, during and after treatment
9.7.3.12 <del>documentation of patient</del> monitoring of patient during IVIT in addition to vitals
9.7.3.13 how treatment was tolerated
9.7.3.14 any adverse reactions to the IVIT and follow up to reactions as needed
9.7.3.15 post-treatment instructions for the patient (when applicable).
9.8.1 All Type 1 occurrence reports are filed in the patient file and a master file.
9.8.2 All Type 2 occurrence tracking forms are filed in the patient file and a master file.
<b>9.9 Delegation Charting</b>
9.9.1 The documentation when a Registrant makes <del>accepting or receiving</del> a delegation includes:
9.9.1.1 The date of the delegation. <del>and the specific activities that were delegated,</del>
9.9.1.2 The <del>date and the specific activities that were delegated,</del> particulars of the delegation.
9.9.1.3 Any applicable conditions.
9.9.1.4 The communication plan to deal with the management of any adverse events that may occur as a result of the delegation.
9.9.1.5 The name and registration number <del>and discipline</del> of the delegator.
9.9.1.6 The name, <del>registration number (if applicable) and training</del> of the delegatee.
9.9.1.7 Informed consent specific to the delegation.
9.9.2 The documentation when a Registrant <del>accepts or receiving</del> a delegation includes:
9.9.2.1 The date of the delegation. <del>and the specific activities that were delegated,</del>
9.9.2.2 The <del>date and the specific activities that were delegated,</del> particulars of the delegation.
9.9.2.3 <del>any applicable</del> The conditions, if any, under which the delegation occurred.
9.9.2.4 The name, registration number and discipline of the delegator.
9.9.2.5 The education and qualifications related to the delegated procedure of the delegator.
9.9.2.6 The name, <del>registration number (if applicable) and training</del> of the delegatee.
9.9.2.7 The period of time the delegation remains in force.
9.9.2.8 Informed consent specific to the delegation.