The College of Naturopaths of Ontario

Inspection Program Requirements for New Premises – Part II

The mandate of the College of Naturopaths of Ontario (the College) is to operate, manage and administer its statutory obligations under the *Regulated Health Professions Act, 1991*, (RHPA) and the *Naturopathy Act, 2007*, to regulate the profession of naturopathy in the public interest.

The Inspection Program of the College supports continuous quality improvement through the development and maintenance of requirements for all premises in which compounding for and/or administration of Intravenous Infusion Therapy (IVIT) are performed. The College recognizes the importance of maintaining competency for certain procedures that are associated with an increased risk, and has developed the Inspection Program to ensure the safety and quality of care for the people of Ontario who chose to access these services.

The Inspection Program Handbook discusses the details of the Inspection Program.

The following outlines the Inspection Program Requirements that are expected to be in place at all times. The exact way in which all the requirements will be met may vary from premises to premises depending on a number of factors such as the square footage, number of practitioners and volume of IVIT treatments provided. There is not necessarily one correct way to implement the requirements. It is left to the judgment of the designated registrant to determine how the requirements can be met in their premises.

1.0 Physical Requirements	
1.1 General	1. IV drugs/substances are located adjacent to the compounding area and in a low traffic area with controlled, limited access.
1.2 Infection Control	1. A telephone, in person or online infectious disease screening protocol consistently is implemented when communicating with patients and scheduling appointments.
1.3 Emergency Measures	1. The AED is fully stocked, the AED pads are not expired, the battery is fully charged, and the unit is fully operational. 2. A crash cart is immediately available and fully stocked.
2.0 Equipment and Supplies	
2.1. Maintenance	1. Laminar air flow hood has been certified as recommended by the manufacturer. 2. Equipment used for administering IVIT is maintained and inspected regularly for functionality and is recorded in the applicable log. 3. Equipment used for compounding for IVIT is maintained and inspected regularly for functionality and is recorded in the applicable log. 4. Cleaning and disinfecting of patient surfaces, equipment, and instruments is recorded in a cleaning log.
2.2 Items	1. Alcohol

Required on the Crash Cart	2. Angiocatheters 3. Atropine i.v. 4. Calcium chloride and/or calcium gluconate and/or calcium glycerophosphate i.v. 5. Dextrose 5% (D5W) and 50% i.v. 6. Diphenhydramine hydrochloride i.v., i.m. 7. Epinephrine hydrochloride i.m. 8. Ipratropium bromide 9. IV tubing and administration sets 10. Magnesium chloride and/or magnesium sulfate i.v. 11. Micropore tape 12. Nitroglycerin 13. Non-latex gloves 14. Non-latex tourniquets 15. Oxygen tank with regulator 0-10 L/min with mask or nasal canula 16. Pocket mask for cardiopulmonary resuscitation 17. Resuscitation bag with O_2 attachment 18. Safety engineered needles 19. Salbutamol 20. Saline bags 21. Smelling salts (amyl nitrate) or essential oil (peppermint) 22. Syringes
2.3 Equipment and Supplies 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 clock with second-hand present in the room)
3.0 Drugs and Substances Storage and Inventory	1. Only drugs/substances listed on Tables 2 and 5 of the *General Regulation* are stocked for compounding for and/or administering by IVIT. 2. Drugs/substances not listed on Tables 2 and 5 of the *General Regulation* are stocked for compounding for and/or administering by IVIT only when a delegation is in place. 3. An IVIT drug/substance inventory record, which includes expiration dates and lot numbers, is maintained and up to date.

	4. IVIT drugs/substances are labelled to indicate the date they were initially punctured. 5. Once a singe-use vial has been punctured it must be used within 12 hours. 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. 7. IVIT drugs/substances are stored according to manufacturer's recommendations, e.g. room temperature, refrigerated, away from light. 8. IVIT drugs/substances requiring refrigeration are stored in a refrigerator dedicated to injectable drugs/substances only. 9. A refrigerator temperature log is maintained and up to date. 10. Expired or contaminated drugs, substances and equipment are labelled and stored separately from current products, to ensure they are not used before being properly discarded. (May use the Ontario Medications Return Program).
4.0 Observation of Compounding IV Bag	
4.1 Compounding IV Bags	1. Laminar airflow hood (LAFH) has been turned on at least 30 minutes prior to use. 2. LAFH is cleaned with sterile 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes before and after use. 3. Verify proper IVIT formula (whether compounded on site or by a compounding pharmacy) and the intended patient. 4. Calculate osmolarity before compounding. 5. All needed bags, vials, and containers are collected and checked for: • beyond use date, • concentration, • leaks, • defects that could compromise sterility, and • abnormal appearance – cloudiness, colour, and precipitate. 6. All needed compounding equipment is collected, checked for the expiration date where applicable, and ensured it is new and not previously opened. 7. The person performing the compounding follows proper hand hygiene at the beginning, and before donning gloves to compound under the laminar air flow hood in accordance with *PIDAC – Infection Prevention and Control for Clinical Office Practice.* 8. The person performing the compounding dons a mask, gown, and gloves at a minimum; (hair, shoe, and beard (when applicable) covers are optional). 9. All bottles, vials, containers, and equipment necessary for compounding are disinfected with 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes as they are placed under the LAFH prior to compounding. 10. Sterile items that are in sealed containers designed to keep them sterile are removed from the coverings as they are introduced into the LAFH without being wiped. 11. All objects are suitably placed in the LAFH to provide good airflow with minimal obstruction.

	12. 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. 13. Proper drawing technique is used, (e.g. calcium gluconate is added last or a new needle used, 45^0 angle with bevel up entry into rubber stoppers). 14. All drugs and substances are added to the iv bag and mixed well. 15. Once compounded, the iv bag is checked for leaks, and abnormal appearance - cloudiness, colour, and precipitate. 16. 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. 17. All sharps are disposed of in a puncture-resistant, tamper-resistant, leak-proof sharps container. 18. All materials are disposed of properly. 19. The iv bag label is disposed of in a secure manner, such that any identifying information is destroyed or unreadable.
4.2 Labelling	The iv bag, or a document attached to the bag, is properly labelled with the following:
	1. The name of the patient for whom the bag was compounded, or an identification number. 2. The Registrant's name and title, address, and telephone number. 3. The name of the person who compounded the iv bag, and the address and telephone number of the place where the bag was compounded, if different from above. 4. The names and strength of the drugs, substances, and any other ingredients used in the compounding, and the manufacturer if available. 5. The amount or percentage of each of the drugs, substances, and any other ingredients used to make the compounded product and the total quantity of the compounded product in the container. 6. The date that the iv bag was: • prepared • administered to the patient, and • the expiry date. 7. The directions for storage of the iv bag. 8. The directions for use of the iv bag, including dose, frequency, route of administration and any special instructions. 9. Any cautionary information about the drug or substance.
5.0 Observed IVIT Treatment	
5.1 Pre-treatment Preparation	1. The patient is questioned regarding any change in their symptoms, medications, and supplements; consideration has been given to possible new contraindications and if additional diagnostic tests are needed. 2. Informed consent is obtained, and all the patient's questions are answered.

	3. The patient is verified for the IVIT treatment being administered. 4. Equipment needed to administer IVIT is collected: • administration set • alcohol • cotton • gloves • safety engineered needles • tape • tourniquet. 5. Collect iv bags and inspect for leaks, cloudiness, colour, and precipitate. 6. Patient is questioned regarding: • use of restroom, and • the last time they have eaten. 7. The person administering the IVIT washes their hands and dons gloves. 8. Clean and dirty fields are established. 9. Appropriate items are placed in the clean field. 10. Pre-treatment vital signs are taken: • blood pressure, • heart rate, • respiratory rate or pulse oximeter reading, and • temperature. 11. All relevant pre-treatment information is entered in the patient chart. 12. The administration set is attached to the iv bag and the line is flushed. 13. The drip chamber is set to half full.
5.2 Delivery and Termination of IVIT	1. The patient's arm is properly positioned and supported. 2. The tourniquet is applied. 3. The appropriate injection site is selected. 4. The injection site is swabbed with 70% isopropyl alcohol. 5. The angiocatheter or butterfly needle is inserted. 6. The angiocatheter/needle is checked for a back flow of blood (flashback). 7. The tournquet is released. 8. The administration line is attached. 9. The angiocatheter/needle is taped and secured. 10. The iv drip is started and the drip rate set. 11. The insertion site is monitored during the treatment. 12. The patient's vital signs are monitored during treatment when indicated or for infusions that take longer than 30 minutes to administer: • blood pressure, • heart rate, • respiratory rate or pulse oximeter reading, and • temperature (when indicated). 13. Once the iv bag has been administered, the angiocatheter/needle and tape are

	removed. 14. The angiocatheter/needle is checked to ensure it is intact and there is no breakage. 15. Pressure is applied with gauze or a cotton ball once the angiocatheter/needle is removed. 16. A bandaid is applied or cotton ball taped down over the insertion site. 17. All waste is handled and disposed of properly. 18. All sharps are disposed of in a puncture-resistant, tamper-resistant, leak-proof sharps container. 19. The insertion site is observed post-treatment for redness, swelling or hematoma. Treatment is provided as needed. 20. Post-treatment vital signs are taken: • blood pressure, • heart rate, • respiratory rate or pulse oximeter reading, and • temperature (when indicated). 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. 22. All relevant information is entered on an IVIT-specific treatment form in the patient chart.
6.0 General Infection Control Procedures	1. When administering IVIT, the following are used for only one patient: • needles, • syringes, • bags of iv solution, • administration tubing and connectors. 2. Gloves are used for a single task and are never re-used. 3. Appropriate personal protective equipment is used when necessary to protect against airborne, contact and droplet transmission. 4. Approved and appropriate cleaning and disinfectant products are used to clean and disinfect patient surfaces. 5. Approved and appropriate cleaning and disinfectant products are used to clean and disinfect equipment and instruments. 6. The cleaning and disinfecting log is kept up to date.
7.0 Quality Management	1. The Quality Management Committee meets in accordance with the Policies and Procedures Manual. 2. Staff reviews the Policy and Procedure Manual at least annually. 3. Naturopathic Doctor(s) performance is reviewed as it relates to IVIT processes and procedures. 4. Non-medical staff performance is reviewed as it relates to IVIT processes and

	procedures. 5. Reviews that staff who are involved in delegated procedures are aware of and have met all requirements outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation*. 6. Reviews that all staff are aware of and trained in the clinic's emergency procedures, including use of the AED. 7. Reviews 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. 8. Reviews that staff are aware of how and when to use personal protective equipment (PPE) in order to protect themselves and others. 9. Reviews that staff are aware of procedures to follow in the event of exposure to blood and body fluids. 10. The quality of patient care provided is monitored and evaluated. 11. Patient outcomes are tracked and reviewed. 12. Methods to improve patient care are developed and implemented. 13. Deficiencies regarding policies and procedures are identified and corrected. 14. Reviews that staff are familiar with Type 1 and Type 2 occurrences. 15. Reviews that staff have met the reporting requirements for Type 1 and Type 2 occurrences. 16. Reviews that staff have met the record keeping procedures for Type 1 and Type 2 occurrences that have happened. 17. Type 1 and Type 2 occurrences that have happened are reviewed and the procedures to reduce the risk of future occurrences are reviewed, developed, and implemented. 18. At least annually, a random selection of 5-10 patient records is reviewed to assess for: • adherence to the *Standard of Practice for Record Keeping*, • documentation of informed consent, • completeness and accuracy of entries, • appropriateness of treatment, • follow-up to abnormal laboratory test results. 19. Reviews that accepted standards of infection control practices pertinent to IVIT are being followed. 20. Reviews that cleaning procedures are being followed and the cleaning log is properly maintained. 21. Reviews that IVIT and emergency equipment is being maintained and the maintenance log is properly maintained. 22. Reviews that drug and substance inventory is monitored, and the inventory log is properly maintained. 23. Reviews that drugs and substances are properly stored, and the refrigerator temperature log is properly maintained. 24. Reviews that expired drugs, substances, and equipment are labelled and properly

	disposed of. 25. Reviews that biomedical and non-biomedical waste is being handled and disposed of properly.
8.0 Patient Chart Requirements	All patient charts must be maintained in accordance with the *Standard of Practice for Record Keeping* and contain the following information.
8.1 Appointment Record	1. Registrant's name, clinic name, address, and telephone number 2. Date and time of the appointment 3. Patient's name 4. Duration of the appointment
8.2 Patient Financial Record	1. Treating Registrant's name, clinic name, address, and telephone number 2. Patient's name, address, and telephone number 3. Date of service 4. Fees for naturopathic consultation (billed separately from all other fees) 5. Fees for supplements, injectables, etc are itemized and separate from the naturopathic consultation fee 6. Copies of the receipts provided to patient for all payments 7. Payment amount, method of payment and balance of the account
8.3 General Patient Chart Record Keeping Components	1. Patient's name, address, phone number, and date of birth 2. Indication of who made each entry with a signature and registration number (when applicable), and the date the entry was made 3. Patient name or patient number on each page 4. All pages are in chronological order, consecutively numbered and dated 5. All dates are recorded in a consistent format 6. All entries are made in, at the least, either English or French 7. All written records are legible 8. All written entries are made in indelible ink 9. No highlighter is used over writing 10. Blank spaces are not left between entries 11. A legend of abbreviations is available when other than generally accepted medical abbreviations are used
8.4 Informed Consent	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. 2. Documentation in the form of a notation in the patient record or a consent form that is dated, signed, and witnessed. 3. Any modifications to the consent. 4. If consent is withdrawn, the reason(s) why and what was specifically withdrawn
8.5 Required Electronic	1. A visual display of the recorded information can be provided 2. The record of each patient can be accessed by the patient's name or other unique

Naturopathic Record Components	identifier 3. The recorded information can be printed promptly in chronological order for each patient 4. Protections against unauthorized or inappropriate access are in place (e.g. password protection, encryption) 5. The system maintains an audit trail that: • records the date and time of each entry for each patient • preserves the original content of the record if changed or updated • identifies the person making each entry or amendment, and • is capable of printing each patient record separately
8.6 Required Naturopathic Records Components	1. The chief complaint(s) 2. Health, family, and social history 3. Allergies 4. Patient's history regarding exposure to and infection from methicillin resistant organisms (MROs) 5. Assessment is formulated from information from one or more of the following: • patient's health history, • physical exam with positive/negative findings documented, • lab tests and other diagnostic investigations that are clinically relevant. 6. Blood tests performed in the office are only those listed in the *General Regulation* made under the *Naturopathy Act, 2007* (BTA Bioterrain Assessment, glucose, live blood cell analysis, haemoglobin $A_{1c,}$ mononuclear heterophile antibodies (monospot), free fatty acids, blood group – ABO and RhD). 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). 8. Laboratory tests ordered from an allowed laboratory are only those listed in *Regulation 683* made under the *Laboratory and Specimen Centre Collection Licencing Act.* 9. Review of medications, remedies, and supplements 10. An assessment of the information collected and a diagnosis 11. Proposed treatment plan 12. Name, strength, dosage, frequency, and method of administration for all drugs and substances included in the treatment plan. 13. Relevant communications with or about the patient 14. Relevant referral information, where applicable 15. Relevant subjective and objective information obtained during re-assessments 16. Amendments to a written chart is initialled, dated and indicates what change was made. 17. Amendments are made in the form of additions and not erasures or overwriting.

8.7 Required Information Related to the Delivery of Intravenous Treatment	1. Whether or not the patient has fears/anxiety around IVIT treatment 2. Whether or not the patient has a history of fainting due to needles 3. An IVIT specific form containing the following information: 1. Name and strength of all drugs/substances administered 2. Formula of the iv bag 3. Dosage and frequency 4. Date of administration 5. Infusion site 6. Catheter size 7. Osmolarity 8. Start time 9. End time 10. Drip rate 11. Vital signs - blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature (when applicable); before, during and after treatment 12. Monitoring of patient during IVIT in addition to vitals 13. How treatment was tolerated 14. Any adverse reactions to the IVIT and follow up to reactions as needed 15. Post-treatment instructions for the patient (when applicable)
8.8 Record Keeping for Type 1 and Type 2 Reports	1. All Type 1 occurrence reports are filed in the patient file and a master file. 2. All Type 2 occurrence tracking forms are filed in the patient file and a master file.
8.9 Delegation Charting	
8.9.1 Documentation Required When a Registrant Makes a Delegation	1. The date of the delegation 2. The particulars of the delegation 3. Any applicable conditions 4. The communication plan to deal with the management of any adverse events that may occur as a result of the delegation 5. The name and registration number of the delegator 6. The name of the delegatee 7. Informed consent specific to the delegation
8.9.2 Documentation Required When a Registrant Accepts a Delegation	1. The date of the delegation 2. The particulars of the delegation 3. The conditions, if any, under which the delegation occurred 4. The name, registration number, and discipline of the delegator 5. The education and qualifications related to the delegated procedure of the delegator 6. The name of the delegatee 7. The period of time the delegation remains in force 8. Informed consent specific to the delegation