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 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.

Inspections of new premises will be conducted in two parts. Part I includes the requirements that must be in place before a premises can offer IVIT and compounding for IVIT to patients. Only once Part I of the inspection is completed and the premises receives an outcome of a pass or pass with conditions can IVIT and related procedures be performed on patients.

Part II includes the additional requirements that must be in place in order for procedures to be performed safely and competently. Within 6 months of Part I of the inspection being completed, an inspector will arrange to complete Part II. This consists of the aspects of the inspection that includes the observation of procedures (i.e. compounding for and administering IVIT) as well as patient chart reviews.

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 once compounding for and the administration of IVIT are being performed. 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 his or her premises.

2.0 Emergency Preparedness Requirements

2.1 General Emergency Preparedness	1. All staff are aware of and trained in the clinic's emergency procedures.
2.2 Equipment and Supplies Required on	1. Automated External Defibrillator (AED) 2. Alcohol 3. Arm board

Crash Cart or in the Premises	4. Basic dressing supplies 5. Cotton balls 6. Gauze and bandages 7. IV tubing, administration sets and angiocatheters 8. Micropore tape 9. Non-latex gloves 10. Non-latex tourniquets 11. Pocket mask for cardiopulmonary resuscitation 12. Resuscitation bag with O_2 attachment 13. Safety engineered needles 14. Scissors 15. Smelling salts (amyl nitrate) or essential oil (peppermint) 16. Syringes
2.3 Drugs Required on Crash Cart	1. Atropine 2. Calcium chloride and/or Calcium gluconate and/or Calcium glycerophosphate 3. Dextrose 4. Diphenhydramine hydrochloride 5. Epinephrine hydrochloride i.m. 6. Ipratropium bromide 7. Magnesium chloride and/or Magnesium sulfate 8. Saline bags 9. Oxygen tank with regulator 0-10 L/min with mask or nasal canula 10. Salbutamol
2.4 Equipment and Supplies not on Crash Cart but Readily Available	1. Cold compresses, hot packs 2. Natural anxiolytic 3. Non-latex blood pressure cuff 4. Pulse oximeter 5. Snacks (crackers, fruit juices) 6. Stethoscope 7. Thermometer 8. Watch (if no wall clock with second hand present in the room) 9. Lidocaine (topical)

3.0 Infection Control Requirements

3.1 General	1. Annual staff training or updating is complete on infection prevention and proper PPE use. 2. All sharps are disposed of in puncture-resistant sharps containers. 3. Non-anatomical waste is handled and disposed of in such a way as to avoid transmission of potential infections.
3.2 Reception	1. Infection control signs are posted at the entry and at the reception desk.

Area and Waiting Room	2. Alcohol-based hand sanitizer at reception with signage. 3. Tissue boxes are available for staff and patients. 4. Garbage cans are readily available. 5. Personal protective equipment available and used by staff when appropriate. 6. Masks are readily available for patients along with signage for proper use. 7. Reception staff can maintain a safe distance (approximately 1 meter) from patients. 8. A telephone, in person or online infectious disease screening protocol has been developed and implemented for use when communicating with patients and scheduling appointments. 9. A patient segregation area is available when needed. 10. Clean toy and soiled toy bins are used where applicable.
3.3 Staff Hand Hygiene	1. Hands are washed before and after direct patient contact, after removing gloves, before performing invasive procedures (e.g. placing an IV) and after contact with blood, body fluids or contaminated surfaces (even if gloves are worn).
3.4 Use of Gloves	1. Gloves are worn for procedures that might involve contact with blood or body fluids and when handling potentially contaminated patient equipment. 2. Gloves are removed before moving to the next task and/or patient.
3.5 Cleaning Procedures	1. Written protocols and procedures for cleaning the office setting are available. 2. Approved and appropriate disinfectant products are available for patient surfaces, equipment and instruments. 3. A procedure is in place to decontaminate gross spills of blood.

4.0 IVIT Compounding Requirements

4.1 Storage, Inventory and Equipment

4.1.1. IVIT Compounding Drugs Storage and Inventory	1. A general drug/substance inventory record is maintained including expiration dates. 2. When applicable, drugs/substances are labelled to indicate the date the seal was broken. 3. Only drugs/substances listed on Table 2 are stocked for compounding and administering by IVIT. 4. Drugs not listed on Table 2 may be stocked if they are being administered through a delegation. 5. Only drugs/substances approved for use by the College of Naturopaths of Ontario for IV administration are used. 6. Drugs/substances appropriate for paediatric administration are available, if applicable. 7. Drugs/substances are labeled in accordance with the General Regulation and Standard of Practice for Compounding.

	8. Drugs/substances are stored according to manufacturer's recommendations. 9. Drugs/substances are stored in a secure manner in a controlled access area within the compounding area. 10. Drugs/substances are organized for easy access in appropriately labelled bins/cupboards. 11. Drugs/substances requiring refrigeration are properly stored in a dedicated refrigerator, with the temperature check regularly (eg. use of a thermometer that registers maximum and minimum temperatures and has a visual readout externally). 12. Cold chain management is ensured. 13. Drugs/substances are stored in the dark where appropriate. 14. Expired or contaminated drugs/substances are stored and labelled to ensure they are not used, and are discarded appropriately (may use the Ontario Medications Return Program).
4.1.2 Equipment for Compounding IVIT Drugs	1. Tools and receptacles with which drugs are compounded are designed, constructed, maintained, arranged and used in a manner that: • permits effective cleaning of all surfaces using appropriate cleaning agents • limits potential contamination of drugs. 2. All packaging and containers are: • free of identified toxic substances (i.e. PVC, BPA) • food grade • stored in such a way as to avoid contamination.

5.0 Monitoring and Reporting Type 1 and 2 Occurrences Requirements

5.1 Monitoring	1. A copy of any report made to the College of a reportable Type 1 or Type 2 occurrence is provided to the inspector at the time of the inspection.
5.2 Reporting within 24 hours	1. Type 1 occurrences are reported and submitted in writing to the College and the designated Registrant within 24 hours of the event or of learning of the event. Type 1 occurrences are: • the death of a patient at the premises where a procedure was performed • the death of a patient occurring within 5 days after a procedure was performed at the premises • any referral of a patient to emergency services within 5 days after a procedure was performed at the premises • any procedure performed on the wrong patient at the premises • the administration of an emergency drug to a patient immediately after a procedure was performed at the premises • the diagnosis of a patient with shock or convulsions occurring within 5 days after a procedure was performed at the premises

	• the diagnosis of a patient as being infected with a disease or any disease-causing agent after a procedure was performed at the premises, if the Registrant forms the opinion that the patient is or may have been infected as a result of the performance of a procedure 3. Death occurring within the premises should also be reported to the coroner.
5.3 Annual Reporting	1. The Registrant shall report within 30 days of learning of a Type 2 occurrence to the designated Registrant who will submit a report of the number and type of Type 2 occurrences to the College annually. Type 2 occurrences are: • any infection occurring in a patient after a procedure was performed at a premises • an unscheduled treatment of a patient by a Registrant occurring within 5 days after a procedure was performed at a premises • any adverse drug reaction occurring in a patient after a procedure was performed at a premises. An adverse drug reaction for the purposes of the Inspection Program Requirements is defined as a harmful and unintended response by a patient to a drug or substance or combination of drugs or substances that occurs at doses normally used or tested in humans for the diagnosis, treatment or prevention of a disease or the modifications of organic function.
5.4 Report Contents	1. All written reports are to be done on the College's Type 1 and 2 Occurrence Report form and should contain the following information: • type of occurrence, • premise contact information, • date of occurrence, • patient information, • reporting and treating Registrant name and contact information • name of any other staff involved in providing care to the patient, • name of witness(es) to the incident (if applicable) • description of the incident and treatment rendered (if applicable), • outcome, • any other information relevant to the incident.
5.5 Record Keeping	1. Copies of the report are stored in a master file. 2. Notation of the occurrence is made in the patient file.

6.0 Patient Chart Requirements

All patient charts must be maintained in accordance with the Standard of Practice for Record Keeping.	
6.1	1. Contains Registrant's name, clinic name, address and telephone number.

Appointment Record	2. Contains the date and time of the appointment. 3. Contains the patient's name. 4. Indicates the duration of the appointment.
6.2 Financial Record and Patient Receipt	1. Treating Registrant's name, clinic name, address and telephone number are recorded. 2. Patient's name and address are recorded on the receipt. 3. Date of service is recorded. 4. Fees for naturopathic consultation are billed separately from all other fees. 5. Fees for supplements, injectables, etc are listed separately from the naturopathic consultation fee. 6. Receipts are issued for all payments and copies are maintained in the patient financial record. 7. Financial record includes payment amount, method of payment and balance of the account.
6.3 General Patient Chart Record Keeping Components	1. Patient's name, address, phone number and date of birth are documented. 2. Patient chart contains a signed informed consent form. 3. 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 registration number and signature, along with the date the entry was made. 4. Patient name or patient number on each page. 5. All pages are in chronological order, consecutively numbered and dated. 6. A consistent format is used for recording the date. 7. All entries are made in, at the least, either English or French. 8. All written records are legible. 9. All written entries are made in indelible ink. 10. No highlighter is used over writing. 11. There are no blank spaces between entries. 12. All chart entries are recorded as soon as possible after the patient interactions. 13. When other than generally accepted medical abbreviations are used, a legend of abbreviations or codes is available.
6.4 Required Electronic Medical Record Components	1. The system provides a visual display of the recorded information. 2. The system provides a means of accessing the record of each patient by the patient's name 3. The system is capable of printing promptly the recorded information in chronological order for each patient. 4. Confidentiality and privacy is maintained (such as through 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 • is capable of printing each patient record separately.

6.5 Required Naturopathic Medical Records Components	1. The chief complaint(s) is clearly stated, the symptoms are adequately described, the duration of symptoms notes and a functional inquiry is performed. 2. The family history and patient's past history are documented. 3. Allergies are identified and documented. 4. Assessment includes 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. 5. 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 $A_{1c,}$ mononuclear heterophile antibodies (monospot), free fatty acids, blood group – ABO and RhD). 6. 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). *7.* Laboratory tests ordered from an allowed laboratory are only those listed in *Regulation 683* made under the *Laboratory and Specimen Centre Collection Licencing Act.* 8. A review of medications and supplements is documented. 9. An assessment of the information and a diagnosis are documented. 10. The proposed treatment plan is fully documented. 11. Relevant communications with or about the patient are documented. 12. The particulars of any referral made is documented. 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. 14. Relevant subjective and objective information obtained during re-assessments is documented. 15. Any amendments to a written chart is initiated, dated and indicates what change was made. 16. Amendments are only made in the form of additions and not erasures or overwriting. 17. A patient chart is never re-written.
6.6 Delegation Charting	The documentation of accepting or receiving a delegation includes: 1. the date and the specific activities that were delegated, 2. the name, registration number and discipline of the delegator, 3. the name, registration number (if applicable) and training of the delegatee 4. the delegator's education and qualifications related to the delegated procedure 5. any applicable conditions, 6. the period of time the delegation remains in force 7. informed consent specific to the delegation

	8. the communication plan to deal with the management of any adverse events that may occur.
6.7 Required Information Related to the Delivery of Intravenous Treatment	1. Name and strength of all drugs administered 2. Dosage and frequency 3. Date of administration 4. Method of administration 5. How treatment was tolerated 6. An IVIT specific form containing the following information: • infusion site • butterfly size • catheter size • drugs administered including dosage • osmolarity • start time • end time • drip rate • vital sign (blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature) before, during and after treatment • documentation of patient monitoring • reactions noted • follow up to reactions • post treatment instructions

7.0 Observed Compounding Requirements

7.1 Compounding of IV Bags	1. It is verified that the proper IV prescription is being prepared for the intended patient. 2. Osmolarity is calculated. 3. Laminar airflow hood has been turned on at least 30 minutes prior to use. 4. The working counter top and sides have been cleaned with a suitable disinfectant prior to use. 5. Proper infection controls and prevention of contamination procedures are followed when working under the laminar airflow hood. 6. Personnel use protective equipment ofgloves, gown and mask, (hair cover and shoe cover are optional). 7. The person compounding under the laminar airflow hood washes their hands with a suitable antimicrobial at the beginning and when re-entering the aseptic preparation area. 8. All bottles, vials or containers are wiped down with alcohol or disinfectant before being brought into the laminar airflow hood. 9. All objects are suitably placed in the hood to provide good airflow with minimal

	obstruction. 10. All items necessary for the preparation should be placed under the hood prior to commencing the compounding. 11. Direct contact between a sterile product and any non-sterile product should be avoided. 12. Bottles are checked for expiry date, proper concentration, contamination and abnormal appearance. 13. All packages are checked to ensure they are new and not previously opened. 14. IV bags are checked for leaks, contamination and abnormal appearance. 15. Bottles are swabbed with alcohol and left for 30 seconds before puncturing. 16. Proper drawing technique is used, (eg. calcium gluconate is added last or a new needle used, 45 degree angle entry into rubber stoppers). 17. All drugs/substances are added to the bag and mixed well. Finished product is inspected for visible precipitate 18. The iv bag, or a document attached to the bag, is properly labelled with: • an identification number, if applicable • the Registrant's name and title • the name, address and telephone number of the place where the bag was compounded • the name of the patient for whom the bag was compounded • the identification of the drugs, substances and any other ingredients used in the compounding, the names and strength and, if available, the manufacturer • the amount or percentage of each of the drugs, substances and any other ingredients used to make the compounded product and the quantity of the compounded product in the container • the date that the compounded drug was prepared and the date that the compounded drug was administered to the patient • the expiry date of the iv bag, even if the bag is to be used on the same day as it is compounded, • the directions for the storage and use of the iv bag, including its dose, frequency, route of administration and any special instructions • any cautionary information about the drug or substance. 19. The label used is disposed of in a secure manner, such that any identifying information is destroyed or unreadable. 20. All materials are disposed of properly.

8.0 Observed IVIT Treatment Requirements

8.1 Pre-treatment Preparation	1. Patient is re-assessed including a review of symptoms, medications, supplements and diagnostic tests. 2. Patient is verified for treatment being administered. 3. Patient is questioned regarding:

	• use of restroom • fears/anxiety around treatment • history of fainting due to needles • last time they have eaten. 4. Informed consent is obtained and all patient's questions are answered. 5. Pre-treatment vital signs are taken – blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature 6. Ensure infection control procedures are followed – e.g. wash hands, establish clean field. 7. Collect IV equipment: • administration set • alcohol • cotton • gloves • safety engineered needles • tape • tourniquet. 8. Collect IV bags and inspect for leaks and cloudy or abnormal appearance 9. Appropriate IV equipment is placed in the clean field 10. Administration set is properly set up
8.2 Treatment Delivery and Termination	1. Patient is properly positioned and prepared for injection. 2. The IV is inserted and drip started. 3. Patient is monitored during treatment (at a minimum blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature are recorded). 4. IV drip is terminated and all materials are properly disposed of. 5. Vital signs (blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature) are taken after treatment. 6. 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. 7. All relevant information is entered on an IVIT-specific treatment form. 8. Only qualified personnel deliver treatment in accordance with their knowledge, skill and judgment.
8.3 Infection Control	1. Universal precautions are followed 2. Needles, syringes, IV bags, medication, administration tubing and connectors are never re-used. 3. All sharps are disposed of in a puncture-resistant sharps container. 4. Patients are screened for Methicillin Resistant Organisms and infectious diseases. Screening may include history taking and questioning the patient. Questioning can include but should not be limited to determining patients who

	are high risk, who know they have been determined to carry MRO in the past or who have had an MRO infection in the past. 5. Appropriate additional precautions are applied as necessary re: airborne, contact/droplet or contact precautions. 6. Staff wear appropriate Personal Protective Equipment.

9.0 Delegation Requirements

9.1 Making a Delegation	The requirements as outlined in the Standard of Practice for Delegation and Part III of the General Regulation must be met. Before delegating a controlled act, a Registrant ensures that he or she: 1. has the authority under the Naturopathy Act and its regulations to perform the controlled acts of administering by intravenous injection and compounding a drug. 2. has the knowledge, skill and judgment to perform the controlled act safely and ethically. 3. has a naturopath-patient relationship with the patient for whom the controlled act will be performed. 4. has considered whether delegation of the controlled act is appropriate, bearing in mind the best interests and needs of the patient. 5. after taking reasonable steps, is satisfied that sufficient safeguards and resources are available to the delegatee so that the controlled act may be performed safely and ethically. 6. has considered whether the delegation of the controlled act should be subject to any conditions to ensure that it is performed safely and ethically and has made the delegation subject to conditions, if necessary. 7. has put in place a communication plan between himself or herself and the delegatee that deals with the appropriate management of any adverse events that may occur as a result of the delegation. 8. after taking reasonable steps, is satisfied that the delegatee is a person who is permitted to accept the delegation. 9. after taking reasonable steps, is satisfied that the delegatee is a health care provider who has a professional relationship with the patient, a person in the patient's household or a person who routinely provides assistance or treatment to the patient. 10. after taking reasonable steps is satisfied that the delegatee has the knowledge, skill and judgment to perform the controlled act safely and ethically. 11. A Registrant may not delegate a controlled act that was delegated to him or her to perform. 12. If a Registrant who has delegated a controlled act but has reasonable grounds to believe that the delegatee no longer has the ability to perform the controlled act safely and ethically shall immediately cease to delegate the controlled act to the

	delegatee and shall take measures to ensure that the delegatee ceases to perform any controlled acts previously delegated by the delegator but not yet completed. 13. The delegation may be made orally or in writing. 14. Appropriate documentation regarding the particulars of the delegation is maintained and readily available. Documentation should include, but is not limited to, information such as the risk of harm and potential benefits of the procedure, the safeguards in place, education and qualifications of the delegatee, insurance coverage, the communication plan, date of the delegation and conditions under which the delegation occurred.
9.2 Accepting a Delegation	The requirements as outlined in the Standard of Practice for Delegation and Part III of the General Regulation must be met. 1. A Registrant shall not accept the delegation of a controlled act unless the person delegating the controlled act was, at the time of the delegation, a Registrant of another health profession regulated under the RHPA who is authorized to perform that controlled act. 2. A Registrant shall not perform a controlled act that was delegated to him or her by a person to whom the controlled act was delegated. 3. The Registrant ensures appropriate documentation regarding the particulars of the delegation is maintained. Documentation should include, but is not limited to, information regarding the date and specific activities that were accepted, the name, registration number and qualifications of the delegator, any applicable conditions and period of time the delegation remains in force.
	Before accepting a delegation the Registrant ensures that he or she: 4. has the knowledge, skill and judgment to perform the controlled act safely, competently and ethically 5. has a naturopath-patient relationship with the patient for whom the controlled act is to be performed. 6. has considered whether performing the controlled act is appropriate, bearing in mind the best interests and needs of the patient. 7. after taking reasonable steps, is satisfied that sufficient safeguards and resources are available so that the controlled act may be performed safely and ethically. 8. has no reason to believe that the delegator is not permitted to delegate the controlled act. 9. has ensured that any conditions have been met, if the delegation is subject to any conditions.

10.0 Quality Management Requirements

10.1 General	1. Documentation that a Quality Management Committee has been established and is comprised of all staff providing IVIT related patient care.

10.2 Monitoring Quality of Care	1. The premises has a written quality improvement program in place which: • monitors and evaluates patient care, • evaluates methods to improve patient care, • identifies and corrects deficiencies within the premises, • alerts the designated Registrant to identify and resolve problems. 2. Non-medical staff performance is reviewed as it relates to IVIT processes and procedures. 3. Naturopathic Doctor performance is reviewed including patient selection to ensure appropriateness of treatment. 4. Patient outcomes are tracked and reviewed. 5. Complications and Type 1 and 2 occurrences are tracked and evaluated. 6. At least annually, a random selection of 5-10 patient records is reviewed to assess for: • record completion and documentation of informed consent • completeness and accuracy of entries • appropriate patient treatment • when required, reporting requirements are met in a timely manner • evaluation of Type 1 and 2 occurrences • assessment of transfer to hospital • abnormal laboratory results follow-up
10.3 Equipment	1. Review of activities related to cleaning, maintenance and storage of equipment
10.4 Drug Inventory and Storage	1. Review of activities related to monitoring drug inventory and proper storage.
10.5 Reporting	1. A process is in place for the reporting and documentation of Type 1 and 2 occurrences, incompetence or professional misconduct.