The College of Naturopaths of Ontario

Inspection Program Requirements for New Premises – Part I

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. 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: • administration and patient-waiting area/room • IVIT administering area/room • clean utility area/room • non-sterile storage area/room • compounding area/room • recovery area/room. 2. Layout of all rooms/areas facilitates safe, comfortable patient care and patient flow. 3. Premises is neat, clean, and free of clutter. 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. 5. The compounding area/room containing the laminar air flow hood is in a low traffic area controlled, limited access.

	6. A sink is readily available in the premises for staff use. 7. IV drugs/substances are located adjacent to the compounding area and in a low traffic area with controlled, limited access. 8. Electrical outlets are available. No overloaded wall plugs or overloaded extension cords are in use.
1.2 Infection Control	1. Floors, walls, chairs, examination tables, patient contact surfaces, etc. can be cleaned to meet infection control requirements (e.g. surfaces are smooth and washable). 2. Access to hand-washing facilities with proper towel disposal is available to patients and all staff. 3. Alcohol-based hand sanitizer is readily available throughout the premises for staff and patients. 4. Tissue boxes are available throughout the premises for staff and patients. 5. Disposable masks are readily available for patients. 6. Infection control signs are prominently posted. 7. Infection control signage includes how to prevent the spread of infections (e.g. use of alcohol-based hand sanitizer, use of masks, etc.). 8. A telephone, in person or online infectious disease screening protocol has been developed for use when communicating with patients and scheduling appointments. 9. Garbage cans are readily available throughout the premises for staff and patients. 10. Reception staff are protected from possible exposure (e.g. use of personal protective equipment, maintaining a safe distance from patients, or protective barriers are in place). 11. A patient segregation area is available when needed. 12. Clean toy and soiled toy bins are available where applicable.
1.3 Emergency Measures	1. Hallways, stairways, and elevators (where applicable) are sufficiently wide to allow emergency evacuation of a patient by emergency personnel and their equipment. 2. The premises is equipped with fire alarms, smoke detectors and/or a sprinkler system. 3. Fire exits are clearly marked, and evacuation maps are prominently displayed in all patient areas. 4. Notices are posted and readily visible in common areas indicating an AED is on site. 5. The AED is fully stocked, the AED pads are not expired, the battery is fully charged, and the unit is fully operational. 6. There is emergency lighting in all patient areas. Emergency lighting may include but is not limited to a permanently installed emergency system or battery powered portable devices. 7. Emergency procedures are readily available for staff to use in the event of a patient-related emergency. 8. A crash cart is immediately available and fully stocked.

2.0 Equipment and Supplies	
2.1 General	1. All electrical devices meet Canadian electrical safety requirements and contain certification marks, such as CSA, cUL or cETL. 2. Sharps/biohazard containers are puncture-resistant, tamper-resistant, leak-proof with a clearly identifiable biological hazard label. 3. Sharps/biohazard containers are easily accessible in every "point of use" area and mounted out of the reach of children. 4. Laminar air flow hood is in place for premises where compounding for IVIT is conducted. 5. Appropriate personal protective equipment (PPE) is available for procedures where applicable. 6. Spill kit is readily available to clean gross spills of blood.
2.2 Maintenance	1. Laminar air flow hood has been certified as recommended by the manufacturer. 2. Maintenance logs are available to record the maintenance and inspection of equipment used for administering IVIT. 3. Maintenance logs are available to record the maintenance and inspection of equipment used when compounding for IVIT. 4. Approved and appropriate cleaning and disinfecting products are available for cleaning and disinfecting patient surfaces 5. Approved and appropriate cleaning and disinfecting products are available for cleaning and disinfecting equipment and instruments. 6. A log is available to record all completed cleaning and disinfecting of patient surfaces, equipment, and instruments.
2.3 Items Required on the Crash Cart	1. Alcohol 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
2.4 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. An IVIT drug/substance inventory record, which includes expiration dates and lot numbers, is available. 2. IVIT drugs/substances are stored according to manufacturer's recommendations, e.g. room temperature, refrigerated, away from light. 3. IVIT drugs/substances are organized for easy access in labeled bins, cupboards, and shelves, including those in the refrigerator. 4. A dedicated refrigerator is available for the storage of injectable drugs/substances only. 5. The refrigerator used for IVIT drugs/substances is at the correct temperature (2-8 ^{o}C) and monitored with a thermometer that records maximum and minimum temperatures and includes an external visual readout. 6. A refrigerator temperature log is available.
4.0 Policies and Procedures Manual	The Policies and Procedures Manual contains information, policies, and procedures that address the following.
4.1 Administrative	1. Staff person(s) responsible for developing and maintaining the Policies and Procedures Manual. 2. Organizational chart. 3. Scope and limitations of the services provided at the premises. 4. Descriptions for all premises staff who are involved with patients receiving IVIT that define the scope and limitations of their duties and responsibilities.
4.2 Operational Procedures	1. Storage, handling, and disposal of combustible and volatile materials. 2. IVIT drugs and substances handling and inventory.

	3. Cold chain management – storage and handling of drugs and substances requiring a controlled cold temperature. 4. Appropriately scheduled maintenance and/or calibration of IVIT equipment and updating the maintenance log. 5. Documentation for all equipment used for administering and compounding for IVIT: • equipment operating manuals, where applicable, • equipment maintenance contracts, where applicable, • maintenance log • inventory list. 6. Patient preparation for IVIT procedures. 7. Response to latex allergies including accidental exposure in a latex-free clinic. 8. Handling and disposal of biomedical and non-biomedical waste.
4.3 Type 1 and Type 2 Occurrences	1. All staff are aware of what Type 1 and Type 2 occurrences are. 2. All staff are aware of when and whom they must report Type 1 and Type 2 occurrences to. 3. How Type 1 and 2 occurrences are responded to. 4. Record keeping for all Type 1 occurrences, Type 2 occurrence tracking (i.e. filed in the patient file as well as in a master file), and Type 2 occurrence annual reports. 5. Requirement to report a death occurring within the premises to the coroner.
4.4 Emergency Response and Management	1. A risk analysis for the premises, as outlined in the *Standard of Practice for Emergency Preparedness* that includes: • volume of patients • volume of high-risk patients • proximity to a hospital • proximity to an emergency room • acuity of illness of patients • access to emergency services. 2. Management of patient emergencies. 3. Management of emergencies due to fire. 4. Management of emergencies due to power failure. 5. Management of other emergency requiring immediate evacuation. 6. Emergency situations that require 911 to be called. 7. How and when to summon additional staff urgently within the premises. 8. How a patient in urgent need of transfer is to be transferred to hospital (in most cases this would be by ambulance). 9. How the ND most responsible for the patient sends essential information with the patient. 10. How to ensure a regulated health professional accompanies the patient during the transfer.
4.5 Infection	1. Infection control protocols, including cleaning protocols, that adhere to accepted

Control	standards of infection control practices. 2. Protocol to decontaminate gross blood spills. 3. Protocol for cleaning the laminar air flow hood. 4. Protocol for hand hygiene when performing IVIT procedures. 5. A telephone, in person or online infectious disease screening protocol used when communicating with patients and scheduling appointments. 6. When and how staff are to use personal protective equipment to protect themselves and others. 7. Process to ensure all staff who are exposed to blood and/or body fluids are referred for post-exposure prophylaxis.
4.6 Training	1. Processes to ensure completion of staff training for: • infection prevention and control, • proper use of personal protective equipment (PPE), • proper hand hygiene, • emergency procedures, • waste disposal, • inventory handling and storage, • handling gross blood spills, • cleaning equipment and patient surfaces, and • other areas as determined by the premises.
4.7 Quality Management Program	1. Formation of a Quality Management Committee and the staff members, who are involved with patients receiving IVIT, comprising the committee. 2. Frequency and reasons for Quality Management Committee meetings. 3. Staff review of the Policies and Procedures Manual, at least annually. 4. Performance review of naturopath(s) who perform IVIT procedures. 5. Review of staff who are involved in delegated procedures to ensure all requirements outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation* are met. 6. Performance review of non-medical staff involved in any of the premise's IVIT related processes and procedures. 7. Reviewing that staff are aware of and trained in the premise's emergency procedures, including use of the AED. 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. 9. Reviewing that staff are aware of how and when to use personal protective equipment (PPE). 10. Reviewing that staff are aware of procedures to follow in the event of exposure to blood and body fluids. 11. Monitoring and evaluating that quality of patient care provided. 12. Tracking and reviewing patient outcomes. 13. Developing and implementing methods to improve patient care.

	14. Identifying and correcting deficiencies in the premise's policies and procedures. 15. Reviewing all Type 1 and Type 2 reporting and record keeping requirements. 16. Reviewing all Type 1 and Type 2 occurrences that occurred at the premises and developing policies and procedures to reduce the risk of future occurrences. 17. Selecting, at least annually, and reviewing 5-10 patient records to assess: • quality of care to patients, • completeness and accuracy of entries, • documentation of informed consent, • appropriateness of treatment, • follow-up to abnormal laboratory test results, and • adherence to the *Standard of Practice for Record Keeping*. 18. Monitoring adherence to infection control practices pertinent to IVIT. 19. Monitoring proper cleaning procedures for patient surfaces and IVIT equipment. 20. Monitoring maintenance of IVIT and emergency equipment. 21. Monitoring the drug and substance inventory and storage (including cold chain management). 22. Monitoring labelling and disposal of expired drugs, substance, and equipment. 23. Monitoring use of logs for inventory, cleaning, and maintenance. 24. Reviewing proper handling and disposal of all biomedical and non-biomedical waste.
4.8 Delegation	1. Processes to ensure the criteria for **making** a delegation as outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation* are met. 2. Processes to ensure the criteria for **accepting** a delegation as outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation* are met.
4.9 Miscellaneous	1. All forms used at the premises (e.g. intake forms, IV treatment form, consent, Type 1 occurrence report, Type 2 occurrence tracking). 2. Templates of all logs including inventory, maintenance, cleaning, refrigerator temperature, etc. 3. Any external policies, as deemed necessary by each individual premises.