Revisions to the Inspection Program Requirements for New Premises – Part I Inspections are indicated in the table below as follows:

~~Deletion~~ Addition

1.0 Physical Requirements
1.1 General
~~1.1.1 Site complies with all applicable building codes including fire safety requirements.~~
~~1.1.3.1 Access for persons with disabilities complies with provincial legislation (*Accessibility for Ontarians with Disabilities Act*).~~
~~1.2.1.1 Temperature and ventilation ensures staff and patient comfort.~~
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. • administration and patient-waiting area/room • ~~procedure~~ IVIT administering area/room • clean utility area/room • non-sterile storage area/room • compounding area/room • recovery area/room.
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 ~~(separate room or~~ a low ~~and controlled~~ traffic area with controlled, limited access~~)~~.
1.1.6 A sink is readily available in the premises for staff use.
1.1.7 The area where IV drugs/substances will be located is 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.
1.2 Infection Control
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 ~~In premise a~~ 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. ~~along with signage for proper use~~.
1.2.6 Infection control signs are prominently posted. ~~at the entry and at the reception desk~~.
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 has been developed ~~and 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, ~~can~~ 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 available ~~used~~, where applicable.

1.3 Emergency Measures
1.3.1 Hallways, stairways and elevators (where applicable) 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~~/smoke~~ alarms, smoke detectors and/or a sprinkler system. ~~that conforms to local fire codes and fire safety training.~~
1.3.3 Fire exits are clearly marked, and evacuation maps are prominently displayed ~~located~~ 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 ~~care~~ 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 ~~clearly displayed.~~ 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.
2.0 Equipment and Supplies
2.1 General
2.1.1 All electrical devices ~~are certified by CSA or licensed for use in Canada~~ meet Canadian electrical safety requirements and contain certification marks, such as CSA, cUL or cETL.
2.1.2 Sharps/biohazard containers are ~~readily available to staff~~ puncture-resistant, tamper-resistant, leak-proof with a clearly identifiable biological hazard label.
2.1.3 Sharps/biohazard containers are ~~readily available to staff~~ 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.
2.2 Maintenance and Cleaning
2.2.1 Laminar air flow hood has been certified as recommended by manufacturer.
2.2.2 Maintenance logs are available to record the maintenance and inspection of equipment used for administering IVIT.
2.2.3 Maintenance logs are available to record the maintenance and inspection of equipment used when compounding for IVIT.
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 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 ~~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 ~~and Equipment~~

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

3.1 An IVIT ~~general~~ drug/substance inventory record, which includes expiration dates and lot numbers, is available.

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

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

3.4 A dedicated refrigerator is available for the storage of injectable drugs/substances only.

3.5 ~~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)~~.

3.6 A refrigerator temperature log is available.

~~4.1.1.6 Drugs/substances appropriate for paediatric administration are/will be available if applicable.~~

4.0 Policies and Procedures Manual

The Policies and Procedures Manual contains information, policies, and procedures that address the following.

4.1 Administrative

4.1.1 Staff person(s) responsible for developing and maintaining the Policy and Procedure Manual ~~is determined~~.

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 who are involved with patients receiving IVIT that define the scope ~~responsibilities~~ and limitations of their duties and responsibilities ~~for patient care~~.

~~11.2.2 Responsibilities for supervising staff.~~

4.2 Operational Procedures

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 - storage and handling of drugs and substances requiring a controlled cold temperature.

4.2.4 ~~Routine~~ Appropriately scheduled maintenance and/or calibration of IVIT equipment and updating the maintenance log.

4.2.5 ~~The following~~ Documentation for all equipment used ~~when~~ for administering and compounding for IVIT ~~is available included~~:

- equipment operating manuals, where applicable,
- equipment maintenance contracts, where applicable,
- maintenance log,
- inventory list.

~~1.3.2.3 The following documentation for all equipment used for compounding IVIT is available:~~

~~• equipment operating manuals~~

~~• equipment maintenance contracts, where applicable~~

~~maintenance log.~~

~~4.2.7 Patient booking system.~~

~~4.2.8 Obtaining patient informed consent.~~

4.2.6 Patient preparation for IVIT procedures.

4.2.7 Response to latex allergies including accidental exposure in a latex-free clinic.

4.2.8 Handling and disposal of biomedical and non-biomedical waste. ~~and garbage disposal.~~

4.3 Type 1 and Type 2 Occurrences

4.3.1 ~~Ensures~~ All staff are aware of ~~the requirements of when and who to report~~ what Type 1 and Type 2 occurrences are ~~to~~.

4.3.2 ~~Ensures~~ All staff are aware of ~~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~~ when and whom they must report Type 1 and Type 2 occurrences to.

4.3.3 ~~Establishes~~ How Type 1 and Type 2 occurrences are responded to. ~~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.~~

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 ~~should also be reported~~ to the coroner.

4.4 Emergency Response and ~~Safety Precautions~~ Management

4.4.1 A risk analysis for the premises, ~~of the practice is conducted, and documented, based on, at a minimum, the following criteria~~ 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, and
- access to emergency services.

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 ~~by an appropriate transportation service~~ (in most cases this would be by ambulance).
4.4.9 How the ND most responsible for the patient ~~ensures that~~ sends essential ~~medical~~ information ~~is sent~~ with the patient.
4.4.10 How to ensure a regulated health professional ~~staff member~~ ~~should~~ accompanies the patient during the transfer.
~~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.~~
~~11.5.5 The ND most responsible for the patient must complete a report.~~
4.5 Infection Control
4.5.1 Infection control protocols, including cleaning protocols, that ~~Premise~~ adhere to ~~and maintains documentation for~~ accepted standards of infection control practices.
4.5.2 ~~A procedure is in place~~ 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 ~~Referral for post-exposure prophylaxis is recommended for~~ Process to ensure all staff who are exposed to ~~with~~ blood and/or body fluids ~~exposure~~ are referred for post-exposure prophylaxis.
4.6 Training
4.6.1 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 ~~Monitoring Quality of Care~~ Quality Management Program
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 ~~Process to review individual ND~~ Performance review of naturopath(s) who perform IVIT procedures. ~~(procedure selection, patient outcomes, occurrences, etc.).~~
4.7.5 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.
4.7.6 ~~Process to review the~~ 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 ~~Process to~~ Reviewing all Type 1 and Type 2 occurrences that occurred at the premises, ~~including potential remedial actions that may be taken~~ and developing policies and procedures to reduce the risk of ~~prevent~~ future occurrences ~~and mitigate harm to patients~~.to patients.
4.7.17 ~~Process to randomly~~ 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 • ~~to ensure records~~ adherence to the *Standard of Practice for Record Keeping*.
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.
~~11.7.4 Process to review compliance with all policies and procedures in the manual.~~
4.8 Delegation
4.8.1 ~~Delegating controlled acts.~~ 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.
4.8.2 How to meet 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
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.