The College of Naturopaths of Ontario

Inspection Program Handbook

October 2023

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1. Introduction

The College of Naturopaths of Ontario (the College) regulates naturopathic doctors in Ontario in the public interest in accordance with the *Regulated Health Professions Act, 1991*, (RHPA) and the *Naturopathy Act, 2007*. Its mandate is to support patients' rights to receive safe, competent and ethical naturopathic care.

The Inspection Program of the College supports continuous quality improvement through the development and maintenance of standards 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 choose to access these services.

The College conducts all inspections in accordance with Part IV of the *General Regulation*. As indicated in Section 28 of the regulation, it is the duty of every Registrant whose premises are subject to an inspection to cooperate fully with the inspector conducting the inspection and with the College.

The program inspects premises where compounding for, or the administration of IVIT, are performed to ensure that the Inspection Program Requirements, as well as standards, policies and procedures are in place and are being practised by staff within the premises. The Inspection Program provides an opportunity for an inspector to review a premise to ensure that all the College's requirements and expectations are being followed and to provide feedback to the Designated Registrant. It is the role of the Inspection Committee to determine the outcome of the inspection as to whether the premises receives a pass, pass with conditions, or fail.

The Inspection Program Requirements outline the physical environment, emergency preparedness, infection control, equipment and supplies to be stocked and maintained, the policies and procedures manual, compounding for and administering IVIT procedures, record keeping, delegation and quality management criteria that must be met by each premises. The Inspection Program Requirements can all be found on the College's website.

The Inspection Program applies to all premises where administering IVIT or compounding for the purpose of IVIT is offered by Registrants of the College who have met the standard of practice as described in regulation for IVIT and prescribing. The standard of practice in the regulation requires the Registrant to successfully complete a College-approved course and exam on both therapeutic prescribing and administering a substance by intravenous injection.

As such, it is the responsibility of every Registrant who compounds for or administers IVIT to be aware of the Inspection Program Requirements and ensures the premises where they are practising meets the criteria, regardless of the ownership of the premises.

This handbook provides information to help Registrants understand how the Inspection Program works.

2. Terminology

This handbook will use a number of terms that might not always be familiar to the reader. To assist in the reading and understanding of this Handbook, the following terms are used.

Designated Registrant	Means the designated contact person for a premises who is responsible for the administration of the premises in compliance with the Inspection Program.
General Regulation	Means Ontario Regulation 168/15 made under the *Naturopathy Act, 2007*, as amended from time to time.
IVIT Procedures	Means the compounding of drugs or substances for the purposes of administration by IVIT or the administration of IVIT by a naturopathic doctor.
Inspectors	Means an individual appointed by the College under Part IV of the General Regulation and who will review a premises to ensure its compliance with the Inspection Program requirements.
Inspection	Means the process whereby an individual will review a premises to ensure its compliance with the Inspection Program requirements.
Premises	Means any location where a naturopathic doctor performs an IVIT procedure, regardless of who may own the location.
Prescribing	Means the controlled act of prescribing a drug authorized to naturopathic doctors in the tables set out in the General Regulation.
Standards of Practice	Means the minimum standard of professional behaviour and ethical conduct, as well as relevant legal requirements on a specific topic or issue expected by the College. The standards of practice for the profession can be found here on our website.

3. Registering a Premises

3.1 New Premises

For premises where Registrants are not currently, but are intending to perform IVIT procedures, the Designated Registrant must provide written notification of the new premises to the College by completing the online Registering an IVIT Premises form and paying the $100 premises registration fee. When the College receives the form, the Designated Registrant will be sent an invoice for the registration fee. Once payment of the fee is received, the premises will be considered registered and placed in the queue for a new premises inspection.

New premises must undergo a Part I inspection and receive an outcome of a pass or pass with conditions prior to offering the administration of IVIT or compounding for IVIT to patients.

Any premises that has failed an inspection and/or has not remediated any identified deficiencies and met any applicable conditions to the satisfaction of the Inspection Committee will not receive a

final outcome of a pass or a pass with conditions. In these cases, they must register as a new premises, pay the premises registration fee, undergo Part I of the inspection, and receive an outcome of a pass or pass with conditions before starting/resuming IVIT procedures.

All Registrants intending to perform compounding for or administering IVIT at a new premises should confirm that a Designated Registrant has been established, that they have registered the premises and that it has undergone Part I of the inspection and received an appropriate outcome before performing any IVIT-related procedures.

Please note that if a registered premises moves to a new location where IVIT is not currently being performed, the new location must be registered and undergo an inspection before offering IVIT procedures at the new location.

3.2 Existing Premises

For all premises where procedures were being performed on March 2, 2017, the day Part IV of the *General Regulation* came into force, the Designated Registrant was required to register the premises with the College within 60 days (no later than May 1, 2017) by completing the Registering an IVIT Premises form if they intended to continue providing IVIT procedures. These clinics are considered to be existing premises in the Inspection Program.

Please be aware that an existing registered premises that moves to a new location where IVIT is not currently being performed is considered to be a new premises and must register and undergo an inspection before offering IVIT procedures at the new location.

All premises that are registered with the College (whether initially registered as existing or new) will be considered existing premises at the time they are due to have their five-year inspection completed.

4. Ceasing to Perform IVIT

When a premises closes or ceases to offer the services of compounding for or administering IVIT, the Designated Registrant of that premises must notify the College, by submitting the online Cease to Perform IVIT form, no later than **30 days** following the date the premises closed or ceased to offer these services.

In the case of a premises that has been notified that it has been selected for an inspection and then subsequently chooses to close or cease to perform compounding for or administering IVIT, the Designated Registrant must submit the **Cease to Perform IVIT** form in order to stop the inspection from being conducted. This form must be submitted no later than 7 days prior to the inspection to avoid having to pay the inspection fee.

If the premises is later re-opened (intends to resume performing IVIT procedures), the premises will be considered to be a new premises and is required to register, undergo a Part I inspection, and receive an outcome of a pass or pass with conditions before offering IVIT services to patients.

5. Inspection Timelines

5.1 New Premises

For new premises, Part I of the inspection will be completed within 180 days of the College receiving the Registering an IVIT Premises form and the premises registration fee. Within approximately six months of the Part I inspection being conducted, a Part II inspection consisting of aspects of the inspection that can only be done once procedures are being performed, will be completed.

5.2 Subsequent Five-year Scheduled Inspections

Following the initial inspection for existing premises and Part II for new premises, all premises will be inspected once every five years. However, the College may inspect premises more often if it deems necessary or advisable to do so.

6. Notification of Inspection

The College will notify the Designated Registrant in writing of a pending inspection for the premises. The notification will include information regarding the forms and documents that are to be submitted to the College before an inspector can be assigned and the inspection scheduled.

The following are to be submitted to the College within 14 days of the date of the notification:

- Pre-inspection Information form,
- Registrant's Declaration of a Conflict of Interest form, and
- the Policies and Procedure Manual for the premises.

The Pre-inspection Information form is to be completed by the Designated Registrant for an existing premises, or for a Part II of a new premises inspection in order to provide the College with the premises' current contact information and details regarding all staff who provide IVIT-related patient care.

The Conflict of Interest Declaration form ensures that the inspector who might be assigned to complete the inspection and any of the naturopathic doctors, regulated health care professionals or other staff who provide IVIT-related care to patients do not have a conflict of interest. The College makes the final determination as to the existence of a conflict of interest based on the information provided.

A conflict of interest exists where a reasonable person would conclude that the inspector's professional, personal, or financial relationship to one or more of the staff or health care practitioners providing IVIT-related patient care at the premises being inspected may affect their judgment or the discharge of their duties to the College. A conflict of interest may be real or perceived, actual or potential, direct or indirect.

The Policies and Procedures Manual outlines the operations of the premises and is a requirement for all premises where compounding for or the administration of IVIT are performed. The details of what needs to be included in the manual can be found on page 8 of this handbook.

Once the College receives all the necessary information and documentation, the Designated Registrant will be provided with the name of the inspector assigned to conduct the inspection. The inspector will contact the Designated Registrant directly to arrange an inspection date and time

within approximately 30 days.

7. Inspection Program Fees

The Inspection Program is a self-financing program. That is, the cost of operating the program is covered by the inspection fees charged to the premises. The College has based the fees on the costs of inspecting each premises, as well as the administration costs, and the per diems and expenses for inspectors and Inspection Committee members. The fees charged are set out in Schedule 3 of the College's by-laws.

The Designated Registrant will be invoiced for the inspection fee when they are notified that the premises has been selected for an inspection. They are responsible for ensuring the payment is received by the College within the stated timeframe. If payment is not made on or before the required date, the certificate of registration of the Designated Registrant may be suspended for failure to pay fees.

The inspection fee is charged per premises and not per Registrant. For a premises where more than one Registrant performs IVIT, it is up to the premises to determine whether the fee will be divided among Registrants performing IVIT procedures at the premises.

The Inspection Program fees are:

- Premises Registration $100 (+ HST)

  Payable when a premises registers as a new IVIT premises. The fee is non-refundable even if a premises decides to cancel their registration. For a premises that undergoes the Part I inspection, the $100 fee will be applied to the new premises inspection fee.

- New premises $2,500 (+ HST)

  The inspection of a new premises is conducted in two parts, incurring additional expenses as an inspector must attend a premises multiple times (requiring more per diem and travel costs).

- Five-year scheduled inspection $2,000 (+ HST)

  Following the initial inspection for existing premises and Part II for new premises, all premises will be inspected once every five years.

- Inspection Committee ordered inspection $2,000 (+ HST)

  The Inspection Committee can determine if a follow-up inspection is necessary on a case-by-case basis. If a premises fails an inspection or passes with conditions that limit the performance of procedures due to patient safety concerns, an additional inspection may be required to ensure the issues have been rectified prior to the premises being allowed to resume performing procedures.

8. Role and Responsibilities of the Designated Registrant

All premises where IVIT procedures are performed must have a Designated Registrant at all times. The Designated Registrant must be a naturopathic doctor who holds a General class certificate of registration with the College and has met the standards of practice for IVIT and therapeutic prescribing.

For a premises where there is only one naturopathic doctor qualified to perform IVIT procedures, they must be the Designated Registrant. In the case of a premises with multiple qualified naturopathic doctors, one of the Registrants must assume the role.

The following outlines the responsibilities of the Designated Registrant.

8.1 Regulated and Non-Regulated Staff

The Designated Registrant ensures that:

- all regulated health care professionals, including NDs and non-NDs, have the appropriate qualifications and meet the requirements of their respective regulatory bodies, and only perform the procedures that are within their scope of practice, and individual knowledge, skill, and judgment,
- all health care professionals providing IVIT are upholding the standards of practice of their profession and the standards set out in the IVIT Inspection Program,
- all non-regulated staff who are involved in IVIT-related patient care have the appropriate qualifications, and the training to perform the procedures safely, and
- records for every regulated health care professional and non-regulated staff working at the premises are on file, are kept current, and include qualifications and relevant experience.

8.2 Communications with the College

All College requests for information and documentation are to be responded to by the Designated Registrant in the form and timeframe required. All Inspection Program forms are online forms and can be found here.

The Designated Registrant is responsible for completing and submitting the following forms and information.

Document	Details
Registering an IVIT Premises form	Submitted for a new premises or when a premises changes its location in order for Part I of the inspection to occur prior to performing IVIT procedures.
Pre-inspection Information and Registrant's Declaration of a Conflict of Interest forms	Submitted within 14 days once notified of a pending inspection. The link to these forms is provided to the designated Registrant in the notification letter.
Policies and Procedures Manual	Submitted within 14 days once notified of a pending five-year or a new premises Part I inspection.
Deferral Request form	Submitted within 14 days of being notified of a pending inspection if the Designated Registrant

	requires additional time to submit the documentation or to schedule the inspection.
Cease to Perform IVIT form	Submitted no later than 30 days following the date a premises closes or ceases to perform compounding for and/or the administration of IVIT at the current location. Once the form is received the IVIT Premises Register is updated indicating that the premises is inactive.
Adding an IVIT Procedure form	Submitted when a premises that only performed either compounding for or administering IVIT begins to perform both IVIT procedures. The premises will not be inspected at the time a new procedure is added.
Change of Designated Registrant, IVIT Registrants, or Health Professional Corporations form	Submitted when: ○ a person filling the role of the existing Designated Registrant changes. The College must be notified immediately of the new Designated Registrant, ○ a Registrant joins the premises and begins to performs IVIT procedures, ○ a Registrant who performed IVIT procedures leaves the premises, ○ a Registrant already practising at the premises begins to perform IVIT procedures, ○ a Registrant remains at the premises but no longer performs IVIT procedures at that location, or ○ a Registrant who performs IVIT has a health professional corporation, and any of the above changes apply. Once the form is submitted the IVIT Premises Register will be updated to reflect the changes.
Post-inspection Questionnaire	Submitted preferably within 14 days of the inspection. Registrants are provided with a link to the questionnaire when they receive the inspection outcome. Feedback about the Inspection Program and the inspection itself help the College to continually improve the program and better protect the public and patients.

Inspection outcome submission	Within 14 days of the date an inspection outcome of a pass with conditions or fail is received the Designated Registrant may make a submission in response to an outcome to demonstrate how the identified deficiencies have been rectified. The submission is not mandatory; however, if the Designated Registrant does not provide a submission, the outcome will remain in place until the next scheduled inspection. Providing a submission allows the Inspection Committee to consider changes that have been made and may issue a final outcome of a pass or pass with conditions. The submission may be drafted along with other IVIT Registrants at the premises, but it is to be submitted by the Designated Registrant.
Type 1 Occurrence Report form	Submitted within 24 hours of learning of a Type 1 occurrence. See page 16 for more information about monitoring and reporting Type 1 occurrences.
Type 2 Occurrence Annual Report form	Submitted on or before May 1. All Type 2 occurrences that occurred at every premises that was active during the March 2 to March 1 reporting period must be submitted annually. See page 16 for more information about monitoring and reporting Type 2 occurrences.

8.3 Payment of the Inspection Program Fee

The Designated Registrant must ensure that the inspection fee is paid in full and on time. Should the Designated Registrant fail to meet this requirement, their registration may be suspended for failure to pay fees.

If a notification of a late fee payment is sent to the Designated Registrant, in accordance with Schedule 3 of the College's by-laws, a $50 administrative fee for notices for failure to provide information or a form to the College within the specified timeframe may be charged.

8.4 Before, During and After the Inspection

Before the inspection, the Designated Registrant will need to complete and submit the Pre-inspection Information, Declaration of a Conflict of Interest form, and pay the applicable inspection fee. Information regarding this will be included in the letter notifying them of a pending inspection.

The Designated Registrant will be contacted by the inspector to schedule the time and date of the inspection within 30 days.

The Designated Registrant ensures that:

- all requirements outlined in the Inspection Program Requirements and this handbook are in place and being followed by the appropriate staff member(s),
- the Policies and Procedures Manual contains all documentation outlined in the Inspection Program Requirements and is kept current. Information as to what should be included in the manual can be found on page 8 of this handbook,
- the policies and procedures contained in the manual are followed by the applicable staff members and practitioners at the premises,
- the premises maintains all necessary insurance and that individual NDs who compound for or administer IVIT have adequate professional liability insurance in accordance with Section 19 of the College's by-laws. The by-laws can be found here,
- on the day of the inspection, all documentation relevant to the performance of procedures is made available to the inspector, including but not limited to policies, appointment books, reports, and patient records as applicable to the inspection,
- patient records are established and maintained in accordance with the College's *Standard of Practice for Record Keeping*,
- on the day of the inspection for an existing premises and Part II for a new premises, ten patient records are available for the inspector to review. The records chosen should be a good representative of patients receiving IVIT at the premises. In the case of a premises with multiple IVIT naturopathic doctors, the records chosen must include at least one for each of the IVIT NDs, and
- on the day of the inspection for an existing and Part II for a new premises, a patient is scheduled for IVIT and is informed that portions of their treatment will be observed by an inspector.

9. Policies and Procedures Manual

All premises where IVIT procedures are performed must have a Policies and Procedures Manual as outlined in the Inspection Program Requirements. The following information is intended to provide guidance as to what should be included; however, different practice environments will determine the specific needs of each premises that is to be reflected in the policies and procedures of the premises.

The Policies and Procedures Manual must contain the following information.

9.1 Administrative

- Development and maintenance of the manual
    - Outlines which staff member or members develop and maintain the manual. While the Designated Registrant may take on the responsibility of developing the manual, as well as making sure it is kept up to date. Alternatively, they may designate another staff member to take on this responsibility; however, it is the role of the Designated Registrant to oversee the process to develop and maintain the manual as stated in this policy.

- Organisational chart
  - Includes a diagram showing the structure of the organisation and the relationships of the staff positions/jobs.
- Scope and limitations of the services provided at the premises.
  - Describes the scope and limitations of all IVIT and compounding related procedures that are provided at the premises.
- Scope and limitations of staff who provide IVIT-related patient care at the premises.
  - Job descriptions are to be included for all premises staff who are involved with providing some aspect of IVIT-related patient care and compounding. The descriptions should include the scope of care including what controlled acts they are allowed to perform, as well as each person's responsibilities and limitations for patient care.

9.2 Operational Procedures

All premises must have policies and related procedures that address operations within the premises. The manual must include, at a minimum, the following information.

- Storage, handling, and disposal of combustible and volatile materials
  - Ensure all staff are aware of the precautions and procedures required for safe storage, handling, and disposal of any combustible or volatile materials, such as therapeutic oxygen, on the premises.
- Handling and inventory of drugs and substances related to IVIT
  - Include which staff are responsible for ordering and stocking IVIT drugs and substances, the processes for ordering, stocking, proper storage, cold chain management, maintenance of inventory logs, and safe disposal.
- Equipment maintenance
  - Include which staff are responsible for ensuring all equipment used for IVIT procedures is maintained in accordance with the manufacturer's recommendations, as well as maintenance schedules, manuals, inventory lists, maintenance contracts, and procedures for completing the applicable logs.
- Patient preparation for procedures
  - Include the procedures required to prepare patients for IVIT, and the staff member who is responsible.
- Latex allergies
  - If products containing latex are used on the premises, detail how an allergic reaction by a staff member or patient is to be handled, and by whom.
  - If products with latex are not to be used on the premises, it should be made clear that all steps are taken to avoid their use. This does not mean a policy is not needed, as there may be an instance where latex products are unintentionally brought on site and used.
- Waste and garbage disposal
  - Include procedures to ensure all waste is disposed of properly, safely, and in

compliance with the *Standard of Practice for Infection Control*.

9.3 Type 1 and Type 2 Occurrences

All premises must have policies and procedures to ensure that monitoring, reporting, reviewing, and responding to Type 1 and Type 2 occurrences, as required in Sections 24 and 25 of the *General Regulation* and the Inspection Program Requirements, are followed. Policies and procedures to ensure the following are addressed are the minimum of what should be included in the manual.

- All staff are aware of the requirements to report Type 1 and Type 2 occurrences as outlined in Section 25 of the *General Regulation*.
- All staff are aware of the possible Type 1 and Type 2 occurrences that can happen, how staff are to ensure they are reported to the College and the Designated Registrant and recorded in the patient file and a master file. Include that it is the responsibility of every Registrant of the College, those who perform IVIT and those who do not, to report Type 1 occurrences directly to the College within 24 hours of learning of the occurrence and to report Type 2 occurrences to the Designated Registrant.
- How to respond to Type 1 and Type 2 occurrences, including the criteria to determine if emergency services are required. In an event where emergency services are not required, ensure the necessary procedures to provide patient care are included.

9.4 Emergency Response and Management

The risk analysis, completed in accordance with the *Standard of Practice for Emergency Preparedness* is to be included in the manual.

All premises must have policies and related procedures related to the management of emergency situations for all patients and specifically for patients when receiving IVIT, including but not limited to:

- patient emergencies,
- Type 1 and 2 occurrences,
- fire,
- power failure,
- other emergencies requiring evacuation,
- when and how to summon additional staff urgently within the premises,
- how a patient in urgent need is to be transferred to a hospital,
- how the ND most responsible for the patient sends essential information with the patient,
- how to ensure a regulated health professional accompanies the patient during transfer, and
- when and how to request help by 911.

9.5 Infection Control

Infection control policies and procedures should address the following:

- cleaning and disinfecting procedures that adhere to the *Standard of Practice for Infection Control*,

- decontamination of gross blood spills,
- cleaning and disinfecting the laminar air flow hood in premises where compounding occurs,
- proper hand hygiene when performing IVIT procedures,
- screening patient for infectious disease when scheduling patients and prior to their appointment,
- when and how staff are to use personal protective equipment (PPE), and
- access to post-exposure prophylaxis for staff who are exposed to blood and/or body fluids.

9.6 Training

Policies and procedures regarding how and when staff training for the following occurs:

- 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.

9.7 Quality Management Program

All premises must have a documented process in place to ensure the Quality Management Program, as outlined in the Inspection Program Requirements, is implemented. The manual should outline how and when the following components of the program will be achieved:

- formation of a Quality Management Committee,
- frequency and reasons for Quality Management Committee meetings,
- review of the Policies and Procedures Manual,
- review of regulated and non-regulated staff performance,
- review of individual ND performance (procedure/treatment recommendations, patient outcomes, Type 1 and Type 2 occurrences, etc.),
- review of staff who are involved in delegated procedures to ensure all required criteria are met,
- review of emergency procedures, including use of the AED,
- review of use of infection screening protocols,
- review of use of personal protective equipment,
- review of procedures in the event of exposure to blood or body fluids,
- monitoring and evaluating the quality of patient care provided,
- tracking and reviewing patient outcomes,
- developing and implementing methods to improve patient care,

- review of compliance with all policies and procedures in the Policies and Procedures Manual,
- Identifying and correcting deficiencies in the Policies and Procedures Manual,
- review of any Type 1 and Type 2 occurrences that occurred at the premises, developing ways to reduce the risk of future occurrences,
- 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*.
- monitoring adherence to infection control practices pertinent to IVIT,
- monitoring proper cleaning procedures for patient surfaces and IVIT equipment,
- monitoring maintenance of IVIT and emergency equipment,
- monitoring the drug and substance inventory and storage (including cold chain management),
- monitoring labelling and disposal of expired drugs, substance, and equipment,
- monitoring use of logs for inventory, cleaning, and maintenance, and
- review of proper handling and disposal of all biomedical and non-biomedical waste.

In the case of a premises where there is only one naturopathic doctor performing IVIT procedures, the ND should consider working with an ND at another premises to meet the Quality Management Program requirements.

9.8 Delegation

For premises where delegations occur, the manual must include processes to ensure the criteria for **making** and **accepting** a delegation, as outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation,* are met. For premises that do not make or accept delegations, it is optional to include this section in the policies and procedures manual; however, it is advisable to include the *Standard of Practice for Delegation* and Part III of the *General Regulation* in the manual for easy reference if needed.

9.9 Miscellaneous

- Standard forms used at the premises (intake form, IV treatment form, consent, Type 1 occurrence report, Type 2 occurrence tracking, etc.).
- Templates of all logs including inventory, maintenance, cleaning, refrigerator temperature, etc.
- Additional policies, as deemed necessary by each premises.

10. The Inspection

The following describes what can be expected for a five-year and a new premises inspection.

As stated in Section 28(2) of the *General Regulation*, if an inspector is denied entry or access to a premises, all Registrants must immediately cease to perform all IVIT-related procedures at that premises until an inspection has taken place.

The five-year inspection of a premises will be done in accordance with the Inspection Program Requirements – Existing/5-Year which consists of the observation of the IVIT procedures performed at the premises and a review of:

- the physical layout,
- equipment and supplies,
- storage of drugs and substances being compounded and/or administered by IVIT,
- infection control,
- emergency measures,
- 5-10 patient charts and other documentation related to patient care,
- any reports made regarding Type 1 and Type 2 occurrences at the premises,
- the Policies and Procedures Manual,
- activities of the Quality Management Committee,
- compliance with the Inspection Program Requirements and standards of practice, and
- any other material that is deemed relevant to the inspection.

The inspection of a new premises will be conducted in two parts. Part I will be conducted prior to the new premises opening, in accordance with the Inspection Program Requirements New Premises Part I, and will include the aspects that must be in place before compounding for and/or the administration of IVIT are provided to patients. The inspector will review:

- the physical layout,
- equipment and supplies,
- storage of drugs and substances to be compounded and administered by IVIT,
- infection control,
- emergency measures,
- the Policies and Procedures Manual,
- compliance with the Inspection Program Requirements for Part I and standards of practice, and
- any other material that is deemed relevant to the inspection.

Part II, which will be conducted approximately 6 months after Part I, consists of the aspects of the inspection that can only be done once procedures are being performed, as outlined in the Inspection Program Requirements New Premises Part II. The inspector will come to the premises to observe the procedures of compounding for and/or the administration of IVIT and conduct a review of:

- 5-10 patient charts and other documentation related to patient care,

- compliance with the Inspection Program Requirements for Part II and standards of practice, and
- any reports made regarding Type 1 and Type 2 occurrences at the premises.

At the end of an inspection, the inspector will meet with the Designated Registrant to discuss their observations and anticipated content of the Inspector's Report.

The Inspection Committee will provide the inspection outcome to the Designated Registrant who is to make the report available to all Registrants and staff involved with providing patient care related to IVIT.

Upon receiving an inspection outcome of a pass with conditions or a fail, the Designated Registrant may make a submission in writing to respond to the conditions and identified deficiencies, and to demonstrate how the program requirements that were not met have subsequently been remedied. The submission must be received by the College no more than 14 days after the date of receipt of the outcome.

The Inspection Committee will review the submission and determine if a change of the outcome from a fail to a pass or pass with conditions, or from a pass with conditions to a pass is warranted.

11. Determining the Outcome of an Inspection

The Inspection Committee determines the outcome of an inspection. The Committee reviews the Inspector's Report and any other relevant documentation available when making its decision.

The potential outcomes for an inspection are a pass, pass with conditions, and fail. Pass and pass with conditions outcomes are considered current for a maximum of five years from the date the notification of the outcome is issued; however, inspections can occur more often if, in the College's opinion, it is necessary or advisable to do so.

The following explains the outcome, criteria to determine the outcome, and how the outcome can affect the premises.

Outcome	Criteria and Possible Affects to the Premises
Pass	All Inspection Program Requirements were met or partially met at the time of the inspection. Only minor deficiencies may have been identified which do not pose any risk of harm to patients. As a result: • the premises may provide compounding for and/or the administration of IVIT for patients.

Pass with Conditions	One or more Inspection Program Requirements were not met at the time of the inspection that are significant enough to warrant a condition being placed on the premises. As a result: • the premises may provide compounding for and/or the administration of IVIT to patients with conditions in place, • the premises may have specific restrictions placed on the performance of compounding for and/or the administration of IVIT for patients, • the premises may be required to stop performing compounding for and/or the administration of IVIT for patients, • the Designated Registrant may make a submission in writing to the College within 14 days of receiving the inspection outcome, • a follow-up inspection may be conducted at the Inspection Committee's discretion within 60 days of receiving the written submission, • an outcome of a pass will be assigned if the conditions have been rectified to the Committee's satisfaction.
Fail	Few of the Inspection Program Requirements are met at the time of the inspection or there are significant deficiencies identified that pose a risk of harm to patients and cannot be addressed through conditions. As a result: • the premises may **NOT** provide compounding for and/or the administration of IVIT immediately upon being notified of the outcome, • the Designated Registrant may make a submission in writing to the College within 14 days of receiving the outcome, • a follow-up inspection may be conducted at the Inspection Committee's discretion within 60 days of receiving the written submission, • a pass or pass with conditions will be assigned when deficiencies have been rectified to the Committee's satisfaction, • if the Designated Registrant does not make a submission, the premises will be required to register as a new premises and receive an outcome of a pass or pass with conditions for Part I of the inspection before IVIT procedures can be performed.

12. Staff Qualifications

12.1 Naturopathic Doctors

It is expected that naturopathic doctors manage their patients within the scope of practice of the profession in Ontario and their individual knowledge, skill, and judgment.

Registrants who are compounding for and/or administering IVIT at a premises must hold a valid certificate of registration in the General class with the College of Naturopaths of Ontario and must have met the standards of practice for intravenous infusion therapy and therapeutic prescribing.

All Registrants of the College who are registered in the General class are required to renew (in person) their Health Care Provider Level CPR, or equivalent, certification every 24 months regardless of the CPR certification expiration date.

12.2 Regulated Health Professionals

All other regulated health care professionals who are employed at the premises must be adequately trained and registered with their regulatory body. The individual is expected to uphold the standards of practice of their profession, and only perform procedures that are within their scope of practice, and individual knowledge, skill and judgment.

12.3 Other Staff

All additional staff (those who are not NDs or members of another regulated health profession), who may be involved in IVIT-related patient care, must have the appropriate qualifications and training to perform all procedures safely, competently, and ethically.

The Designated Registrant is responsible for ensuring that all regulated and non-regulated staff at the premises involved in IVIT-related patient care have the proper qualifications and maintains the records related to their qualifications.

13. Delegation

A Registrant of the College may delegate a controlled act, which they are authorized to perform under the *Naturopathy Act, 2007,* in accordance with Part III of the *General Regulation* and the *Standard of Practice for Delegation*. Registrants may also accept a delegation, provided they meet the criteria set out in the *General Regulation* and the *Standard of Practice for Delegation.*

A Registrant may not accept or make a delegation to compound for and/or administer IVIT at a premises if the premises has failed an inspection.

A Registrant may not accept a delegation to compound for and/or administer IVIT at a premises if they have not successfully completed a College approved course and exam on both prescribing and administering a substance by intravenous injection.

14. Monitoring and Reporting of Type 1 and Type 2 Occurrences

All staff must monitor Type 1 and Type 2 occurrences.

Every Registrant must report Type 1 and Type 2 occurrences and should advise the Designated Registrant upon learning of the event in accordance with Section 25 of the *General Regulation* and the College by-laws. Upon receiving an occurrence report, the College will determine whether further action is required, such as an inspection of the premises or an investigation under s. 75(1)(a) of the HPPC.

Who must make the report and the required timeframes for reporting an occurrence to the College differ depending on the type and severity of the event. All Registrants must report Type 1 occurrences to the College within 24 hours of learning of the occurrence. Type 2 occurrences are to be reported to the Designated Registrant who must make a report to the College on an annual basis.

Type 1 occurrences include the following in relation to the performance of compounding for and/or the administration of IVIT:

a) death of a patient at the premises after a procedure was performed,
b) death of a patient within five days of a procedure being performed on the patient,
c) any referral of a patient to emergency services within 5 days after a procedure was performed,
d) any procedure performed on the wrong patient,
e) administration of an emergency drug to a patient immediately following a procedure,
f) the diagnosis of a patient with shock or convulsions occurring within five days of a procedure being performed, and
g) the diagnosis of a patient as being infected with a disease or any disease-causing agent following a procedure, if the Registrant forms the opinion that the patient is or may have been infected as a result of the procedure.

A procedure is defined in the *General Regulation* as:

(a) "any procedure by which any two or more drugs or substances listed in Table 2 or Table 5, in any combination, are mixed, reconstituted, or by any other means made into a customized therapeutic product by a Registrant for the purpose of administration by intravenous injection to a patient, and includes the labelling of such a customized therapeutic product, or
(b) the administration of a customized therapeutic product described in (a) by intravenous injection to a patient by a Registrant."

Type 2 occurrences include the following in relation to the performance of compounding for and/or the administration of IVIT:

a) any infection occurring in a patient in the premises after a procedure was performed,
b) an unscheduled treatment of a patient by a Registrant occurring within five days of a procedure being performed, and
c) any adverse drug reactions occurring after the performance of a procedure.

An adverse drug reaction 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.

To report a Type 1 occurrence, please complete the Type 1 Occurrence Report form that can be found on the College's website.

There is also a Type 2 Occurrence Tracking form on the website which may be used to document Type 2 occurrences. These forms are not to be submitted to the College but are rather provided as a tool that can be used internally by the premises.

The Designated Registrant is required to submit their Type 2 occurrence report to the College prior to May 1st , however the form is available on the website and can be completed after March 2nd.

15. Contact Information

For inquiries about the Inspection Program, please contact the College at the following addresses:

The College of Naturopaths of Ontario
Inspection Department
10 King Street East, Suite 1001,
Toronto, ON
M5C 1C3

Tel: 416-583-6020

Fax: 416-583-6011

inspections@collegeofnaturopaths.on.ca

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