Inspection Program Handbook

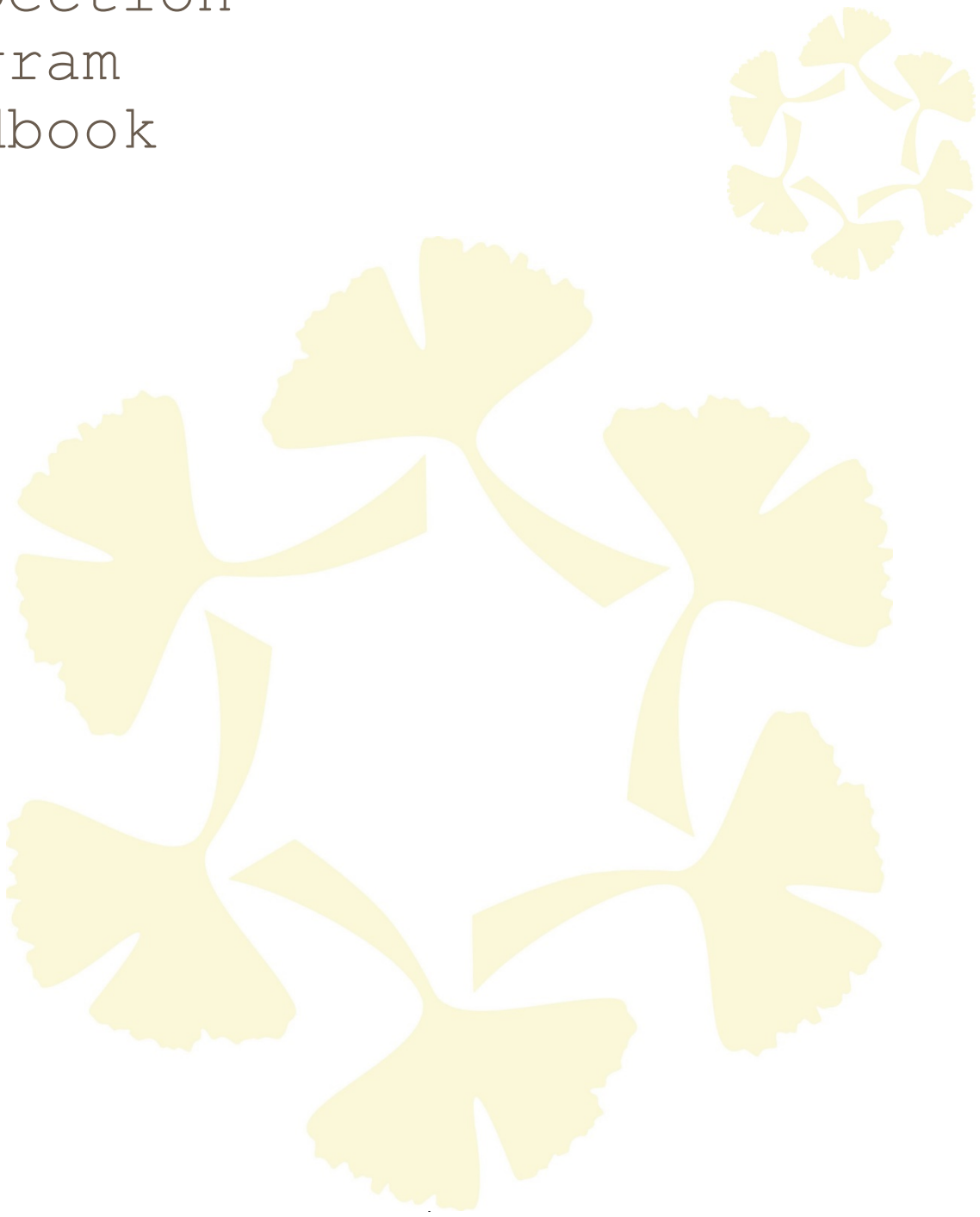

Table of Contents

Introduction

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 standards for all premises in which compounding for and/or administration of Intravenous Infusion Therapy (IVIT) are performed. The College recognises 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 of Naturopaths of Ontario 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 submit to the inspection of the premises where compounding of drugs for or administration of IVIT is performed and to cooperate fully with the inspector conducting the inspection and with the College.

The structure of the program is to inspect premises where compounding for, or 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. Through conducting the inspections, the College recognises that the majority of Naturopathic Doctors are practising safely, ethically, and competently. The Inspection Program provides an opportunity for an inspector to determine that all of the College's requirements and expectations are being adhered to and provides 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 outlines 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 a quality management criteria that must be met by each premises. The Inspection Program Requirements can be found on the College's website.

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

As such, it is the responsibility of every naturopathic doctor who performs compounding for or administers IVIT to be aware of the Inspection Program Requirements and ensures the premises where they are practising meets the criteria.

This handbook addresses the details of the Inspection Program.

The Designated Registrant

All premises in which IVIT procedures are performed must have a designated Registrant at all times. The designated Registrant must be a naturopathic doctor registered with the College who has met the standard of practice for intravenous infusion therapy (IVIT) and prescribing.

The designated Registrant is the contact person for a premises and is responsible for communicating with the College, submitting all Inspection Program forms and ensuring the inspection fees pertaining to the premises are paid. The designated Registrant also ensures that the premises and all staff who perform procedures at the premises meet the responsibilities and requirements outlined in the College's Inspection Program Requirements, Inspection Program Handbook, and Part IV of the *General Regulation*.

All communications from the College will be via e-mail to the designated Registrant.

All the responsibilities of the designated Registrant are discussed in detail on page 6 of this handbook.

Registering a Premises

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.

Any existing premises that did not register during the 60-day period and has continued to provide IVIT procedures is in contravention of Section 31(3) of the *General Regulation*. A premises that did not register with the College must have stopped performing IVIT services as of May 2, 2017. In order to be able to resume these services the premises must register as a new premises, undergo Part I of the inspection and achieve an outcome of a pass or pass with conditions.

All Registrants performing compounding for or administering IVIT at a premises should confirm that a designated Registrant has been determined and that they have registered the premises. A premises is any clinic or location where a Registrant performs IVIT procedures.

Please be aware that a premises that registered as an existing premises and then moves the practice to a new location where IVIT is not currently being performed is considered to be a new premises and must registered as such 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 an existing premises at the time they are due to have their 5-year inspection completed.

New Premises

For premises where Registrants are intending to perform IVIT procedures, the designated Registrant must provide written notification of the new premises to the College by completing

the 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. When payment for the fee is received, the premises will be deemed registered and placed in the queue for new premises inspections.

New premises must undergo Part I of the 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.

For any premises that has failed an inspection and has not remediated the deficiencies and met any applicable conditions to the satisfaction of the Inspection Committee to warrant a final outcome of a pass or a pass with conditions, it 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 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 determined, 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 be aware that a premises registered as a new premises and then moves the practice to a new location where IVIT is not currently being performed is considered to be a new premises and must register as such before offering IVIT procedures at the new location.

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 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 chooses to close or cease to perform compounding for or administering IVIT, the inspection will not be conducted as long as the **Cease to Perform IVIT** form is received by the College at least 14 days prior to the inspection.

If the premises re-opens or resumes performing procedures, the premises will be considered to be a new premises and will be required to register the premises, undergo a Part I inspection and receive an outcome of a pass or pass with conditions before offering IVIT services to patients.

Inspection Timelines

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 6 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.

Subsequent 5-year Scheduled Inspections

Following the initial inspection for existing premises and Part II for new premises, all premises in which compounding for or administering IVIT are performed will be inspected once every 5 years. However, the College may inspect any premises more often if it deems that it is necessary or advisable to do so.

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:

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

The **Pre-inspection Information** form requires the designated Registrant to provide the following information depending on whether the inspection is for an existing premises, or Part I or Part II for a new premises:

- contact information,
- the days and hours when compounding and IVIT are performed,
- a current list of all health care professionals and staff providing IVIT related patient care, and
- the record keeping system used.

This information, along with the information provided in the **Registering an IVIT Premises** form, allows the College to expedite the inspection and reduce the time necessary for onsite collection of information.

The **Registrant's Declaration of a Conflict of Interest** form will ensure that the assigned inspector is not in a conflict of interest with any of the naturopathic doctors, regulated health care professionals or other staff who provide IVIT-related care to patients. The College makes the final determination as to whether or not a conflict of interest exists based on the information provided.

For the purposes of the Inspection Program, 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 a date and time for the inspection to occur within approximately 30 days.

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 to run the program, and the per diems and expenses for inspectors and Inspection Committee members.

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, their registration may be suspended for failure to pay fees. The inspection will be conducted despite a non-payment of the inspection fee.

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 how 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 premise registers a new IVIT premises. If a premises chooses to cancel their registration, the fee is non-refundable. 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 5 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 in order to ensure the issues have been rectified prior to the premise being allowed to resume performing procedures.

Role and Responsibilities of the Designated Registrant

Every premises where compounding for or administering IVIT is offered must have a designated Registrant at all times.

The designated Registrant must be a naturopathic doctor who holds a certificate of registration with the College and has met the standard of practice as described in the regulation for IVIT and 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 practitioners must be appointed to the position.

The designated Registrant ensures that the premises and all staff who perform IVIT procedures meet the College's standards of practice, guidelines and policies, requirements and responsibilities outlined in this handbook, the Inspection Program Requirements and the *General Regulation*. They are also the contact person for any communications related to the premises; the premise's inspection outcome will be directed to the designated Registrant for review and response.

The following outlines the responsibilities of the designated Registrant.

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 are upholding the standards of practice of their profession,
- 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.

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. Inspection Program forms can be found here.

The designated Registrant is responsible for completing and submitting the following:

- for a new premises or when a premises changes its location, the **Registering an IVIT Premises** form, to the College in order for Part I of the inspection to occur prior to performing IVIT procedures.
- once notified of a pending inspection, the **Pre-inspection Information** and **Registrant's Declaration of a Conflict of Interest** forms, within 14 days.
- once notified of a pending inspection, the Policies and Procedures Manual, within 14 days.
- once notified of a pending inspection, the Deferral Request form, within 14 days if the designated Registrant will not be available to attend the inspection for reasons due to extenuating circumstances.
- Cease to Perform IVIT form, 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.

- Adding an IVIT Procedure form, 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 form, when a person filling the role of the existing designated Registrant changes. The College must be notified immediately by the new designated Registrant.
- Change of IVIT Registrants form when:
    - a Registrant joins the premises and begins to performs IVIT procedures, or
    - a Registrant who performed IVIT procedures leaves the premises, or
    - a Registrant already practising at the premises begins to perform IVIT procedures, or
    - a Registrant remains at the premises but no longer performs IVIT procedures at that location.
- the **Post-inspection Questionnaire**, within 14 days of the inspection.
- a submission in response to an outcome of a pass with conditions or fail that demonstrates how the deficiencies have been rectified, within 14 days of the date the outcome was received. 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 to the College by the designated Registrant.
- the Type 2 Occurrence Annual Report, on or before May 1.

Payment of the Inspection Program Fee

The designated Registrant must ensure that the inspection fee is paid to the College 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.

Before, During, and After the Inspection

Before the inspection, the designated Registrant will need to complete and submit the **Pre-inspection Information** and the **Registrant's 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,
- all staff at the premises have read the Policies and Procedures Manual and have confirmed this with a signature and date. They also ensure that all staff reviews the Policies and Procedures Manual annually, and confirms this with a signature and date,
- 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,
- 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,
- 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.

Policies and Procedures Manual

All premises where compounding for or administering IVIT are performed must have a Policies and Procedures Manual as outlined 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.

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.

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:

- 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 in 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 in 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 that procedures are in place to ensure all waste is disposed of properly, safely, and in compliance with the *Standard of Practice for Infection Control*.
- Delegation
  - Ensure the requirements described in Part III of the *General Regulation* and the *Standard of Practice for Delegation* are included.
- Maintenance and calibration of equipment
  - Outline who is responsible for ensuring that all equipment is maintained in accordance with the manufacturer's recommendations and the Inspection Program Requirements. Include the procedure to record that the maintenance has been done.

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. The policies and procedures should include the following:

- Ensure all staff are aware of the requirements to report Type 1 and Type 2 occurrences as outlined in Section 25 of the *General Regulation*.
- Ensure 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.
- Establish how Type 1 and Type 2 occurrences are responded to, 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.

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 on 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 emergency evacuation,
- when and how to summon additional staff urgently within the premises,
- how a patient in urgent need of transfer is to be transferred to 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.

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 infection 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.

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.

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,

- 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 to follow 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.

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. 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.

The Inspection

The following is what can be expected during an inspection of an existing and a new premises.

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

The inspection of an **existing premises** will be done in accordance with the Inspection Program Requirements – Existing which consists of the observation of the IVIT procedures performed at the premises and a review of:

- the physical layout,
- equipment,
- storage of drugs and substances being compounded and/or administered by IVIT,
- infection control,
- emergency measures,
- at least 5 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,
- 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,
- 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:

- at least 5 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 the findings and anticipated content of the inspection report. The inspector will also provide the designated Registrant with a **Post-Inspection Questionnaire** form and invite them to complete and return it to the College within 14 days.

The Inspection Committee will provide the inspection outcome to the designated Registrant who should then 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.

Determining the Outcome of an Inspection

The Inspection Committee will determine the outcome of an inspection. The Committee will review the Inspector's Report and any other relevant documentation 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 5 years from the date the notification of the outcome was 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.

Staff Qualifications

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 standard of practice for intravenous infusion therapy, and prescribing. The standard of practice in regulation requires the Registrant to successfully complete a course and exam on both prescribing and administering a substance by intravenous injection that has been approved by the College.

All Registrants of the College of Naturopaths of Ontario are expected to maintain a valid (not expired) Health Care Provider Level CPR certification. Registrants are to recertify their CPR every two years, at a minimum.

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.

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.

Delegation

A Registrant of the College may delegate a controlled act, which they are authorised 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.

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 the 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.

Who must make the report and the required timeframes for reporting an occurrence to the College differ depend 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 5 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 5 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 5 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 will be reminded prior to May 1st that their Type 2 occurrence report is to be submitted to the College.

Contact Information

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