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Intent/Purpose To provide comprehensive policies governing the Inspection Program of the College of Naturopaths of Ontario (the College).

Definitions	Inspector	A person appointed by the College to carry out an inspection under the Ontario Regulation 168/15 (the <i>General Regulation</i>) on behalf of the College.
	Designated Registrant	A Registrant ¹ who is designated to deliver and accept information on behalf of a specified premises as per Section 30 of the <i>General Regulation</i> .
	Premises	Any place where a Registrant performs or may perform a procedure.
	Procedure	(i) 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 labeling of such a customized therapeutic product, or (ii) the administration of a customized therapeutic product described in (i) by intravenous injection to a patient by a Registrant.
	Adverse Drug Reaction	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.
General	Regulations	All aspects of the Inspection Program will be managed in accordance with the <i>Health Professions Procedural Code</i> , and the Ontario Regulation 168/15. Members of the Inspection Committee (IC) and Professional Practice department staff will act in accordance with these policies, regulations, and the applicable procedures manuals.
	Composition of the Committee	The composition of the IC is specified in the by-laws of the College.
	Quorum	Pursuant to section 12.06 of the By-laws of the College quorum for meetings shall be three (3) members of the Committee unless the Committee is composed of three

¹ The Council of the College of Naturopaths of Ontario has directed that the College refer to individuals registered with the College as “Registrants”. “Registrant”, as it is used in this policy has the same meaning as “member” as defined in section 1(1) of the *Health Professions Procedural Code*.

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(3) members, in which case, the quorum for such a Committee shall be two (2) members, at least one of which shall be either a Public member of the Council or a Public Representative.

In cases of urgency as determined by the Chair of the Committee, the public member requirement for the purposes of quorum may be waived.

Bias/Conflict of Interest

Pursuant to the College's by-laws, no member of a Committee can have a real or perceived bias or conflict of interest. If an IC member has a conflict of interest or bias, whether it is real or perceived, they must declare it and should excuse themselves from any discussions and votes pertaining to the matter whenever the matter is tabled.

Committee members must be objective and impartial with respect to the outcome of the matter coming before them for decision. Committee members may be disqualified because of an actual bias or conflict of interest or because of circumstances that give rise to a reasonable apprehension of bias or conflict of interest, even though an actual bias does not exist.

Responsibilities of the Committee

As outlined in Part IV of the *General Regulation* and the Terms of Reference, the IC may do only one or more of the following:

- advise on and recommend to Council the requirements for, and policies and procedures relating to the Inspection Program of the College
- annually review all program policies and related procedures and report to the Council on the outcome of the review and make any recommendations for amendments, ensure appropriate individuals are appointed and trained to perform inspections;
- bi-annually review relevant regulations made under the *Naturopathy Act, 2007*, including but not necessarily limited to Part IV of the *General Regulation*,
- ensure adequate inspections are undertaken and completed in a timely way using appropriate tools and mechanisms,
- determine, after reviewing inspection reports and other material referred to in Part IV of the *General Regulation*:

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- whether the outcome for a premises is a pass, pass with conditions, or fail,
- specify the conditions that shall be attached to each “pass with conditions”,
- deliver written reports as required,
- direct the CEO to refer a Registrant to the Quality Assurance Committee, if the result of an inspection report made by the Committee finds that a Registrant’s knowledge, skill or judgment is unsatisfactory,
- direct the CEO to refer a Registrant to the Inquiries, Complaints and Reports Committee, if the result of an inspection report made by the College finds that a Registrant may have committed an act of professional misconduct or may be incompetent or incapacitated.

Participation As outlined in Section 26(1) of the *General Regulation*, all premises where a procedure is or may be performed by a Registrant in connection with their practice are subject to an inspection by the College.

Non-compliance Failing to comply with any duty or requirement of Part IV of the *General Regulation* may be considered professional misconduct, as outlined in Section 36 of the Professional Misconduct Regulation.

Annual Policy and Standards Review The IC will review the program policies and the Inspection Program Requirements, on an annual basis.

Inspector’s Honoraria and Expenses Inspectors are entitled to an honorarium of \$75 for inspection preparation, \$150 to conduct the inspection and \$75 for drafting the Inspection Report. Reimbursement for expenses will be in accordance with GP 18.04 Per Diems and Expenses.

Inspection Program General Designated Registrant All premises in which 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 standards of practice for Intravenous Infusion Therapy and Prescribing.

Designated Registrant Responsibilities The Designated Registrant is the main contact person for a premises, and is responsible for communicating with the College and the payment of fees regarding the premises and any inspections thereof. The Designated Registrant ensures that the premises and all staff who

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perform procedures there meet the responsibilities and requirements outlined in the College's Inspection Program documents and Part IV of the *General Regulation*.

Registering a New Premises

For premises where Registrants are intending to perform procedures the Designated Registrant must provide written notification of the new premises to the College by completing the Registering an IVIT Premises form. 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.

An already registered premises that moves to a new location must register as a new premises and 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.

Ceasing to Offer Procedures at a Premises

If a premises closes or ceases to perform compounding for IVIT and/or administration of IVIT, the Designated Registrant must notify the College by completing the Cease to Perform IVIT Procedures form within 30 days of the changes.

Resumption of Procedures at a Premises

If a premises re-opens or resumes performing procedures, the premises will be considered to be a new premises and will be required to undergo and pass or pass with conditions Part I of an inspection prior to offering IVIT services to patients. (Part II of the inspection will occur within approximately 6 months of the completion of Part I.)

Inspection Frequency

All premises where a Registrant performs or may perform a procedure are subject to an inspection by the College once every 5 years, following the first inspection or more often if, in the opinion of the College, it is necessary or advisable to do so.

Timelines for New Premises

New premises in which Registrant are intending to perform procedures will undergo Part I of the inspection within 180 days of the College receiving written notification from the Designated Registrant .

Part II of the inspection will occur within approximately 6 months of the successful completion of Part I.

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Policies and Procedures Manual All premises in which procedures are performed must have a Policies and Procedures Manual which includes, at a minimum, the information outlined in the Inspection Program Requirements. The Designated Registrant is responsible for ensuring the manual is created and kept current, and that all staff reviews the manual on an annual basis.

Naturopathic Doctors' Qualifications Registrants who are performing procedures 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 Prescribing.

All Registrants of the College are expected to maintain valid Health Care Provider level CPR certification.

Other Regulated Health Professionals' Qualifications All regulated health professionals (RHPs) who provide IVIT-related care at the premises must be adequately trained and appropriately registered with their regulatory body.

Other Staff Qualifications All additional staff other than 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 their assigned duties safely and competently.

Delegation A Registrant may not make or accept a delegation for compounding or administration by intravenous injection of a substance at a premises that has failed an inspection.

When making or accepting a delegation the Registrant must meet the criteria outlined in Part III of the *General Regulation* and the *Standard of Practice for Delegation*.

Inspection Fees All premises that are subject to an inspection must pay the inspection fees to the College as per Schedule 3 of the by-laws.

The inspection fee will be invoiced to the premises. The Designated Registrant is required to submit payment within 30 days of the date of the invoice.

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The premises registration fee stated in Schedule 3 of the by-laws is payable on receipt of the Registering an IVIT Premises form.

Invoicing of fees For all regularly scheduled 5-year inspections the inspection fee as stated in Schedule 3 of the by-laws will be invoiced upon notification to the Designated Registrant that the premise has been selected for an inspection.

Refunds For a new premises, the inspection fee as stated in Schedule 3 of the by-laws will be invoiced upon notification to the Designated Registrant that the premises has been selected for an inspection.

Non-payment of fees Inspection fees that have been invoiced and/or paid will not be refunded to a premises that withdraws from the Inspection Program even if the premises has not undergone an inspection.

If payment is not received within the required timeframe the Designated Registrant's registration may be suspended for failure to pay fees.

Withdrawal from Inspection Program When a premises closes or ceases to perform IVIT procedures the Designated Registrant of that premises must notify the College in writing no later than 30 days following the date the premises closed or ceased to perform these services.

If a premises has been notified that it has been selected for an inspection and then chooses to close or cease to perform IVIT procedures the inspection will not be conducted as long as the Cease to Perform IVIT Form is received 14 days prior to the inspection.

Type 1 and Type 2 Occurrence Reporting Type 1 and Type 2 occurrences must be reported in accordance with Sections 24 and 25 of the *General Regulation*. Reports shall be submitted to the College using the applicable form.

Type 2 occurrence reports are to be submitted to the College no later than May 1 of each year and shall be for the reporting period of March 2 of the previous year to March 1 of the current year.

Type 1 Occurrence Report Requirements All Type 1 occurrence reports must include the following information:
 i. which Type 1 occurrence happened,

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- ii. the initials, age, and sex of the patient,
- iii. contact information of the Registrant making the report,
- iv. names of all staff involved in providing care for the patient,
- v. the name(s) of any witness to the event (if applicable),
- vi. the time, date and location of the event,
- vii. a description of the incident and any actions taken, or treatment provided,
- viii. the outcome of the event, and
- ix. any other information relevant to the incident.

Follow up on Occurrence Reports Type 1 occurrences will be reviewed by the IC to determine what, if any, further action is required.

A summary of Type 2 occurrences will be provided to the IC and Council on an annual basis for statistical and planning purposes.

Pre-Inspection Selection of an Existing Premises Following the initial inspection, premises will be selected to undergo an inspection once every 5 years or more often if, in the opinion of the College, it is necessary or advisable to do so.

Selection of a New Premises New premises will be inspected as soon as is practicable and no longer than 180 days after receiving the Registering an IVIT Premises form and the premises registration fee.

Notification of Selection The Designated Registrant for a premises will receive written notification that the premises has been selected for an inspection. Notification will occur via email (as well as fax or mail) and as such every Designated Registrant must provide the College an active email address.

Deferral Requests The Designated Registrant for a premises that is selected for an inspection may seek a deferral only under special circumstances such as if they are on parental leave, are on a leave-of-absence, are seriously ill, or if there are other extenuating circumstances.

The Designated Registrant must submit the deferral request to the College within 14 days of the premises being notified of its selection for an inspection unless there are extenuating circumstances that affect the Registrant's ability to submit the application earlier. The request may be accompanied by a letter from a

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Review of Deferral Requests	<p>regulated health care practitioner or other supporting documentation verifying the circumstances for their inability to attend the inspection.</p> <p>All deferral requests will be reviewed by the IC on an individual basis. Deferrals are granted based on the validity and severity of the situation or illness that may prevent the Designated Registrant from submitting the necessary forms or attending the inspection.</p>
Required Forms Submitted by the Designated Registrant	<p>When a premises is notified that it has been selected for an inspection, the College will provide the Designated Registrant with the Pre-inspection Information and Registrant Declaration of a Conflict of Interest forms that must be completed and returned to the College within, at least 14 days.</p>
Assignment of an Inspector	<p>The Chief Executive Officer, or their delegate, will assign an inspector based on the information provided in the Registering an IVIT Premises form and the Declarations of a Conflict of Interest from the Designated Registrant and the inspectors.</p> <p>No Registrant of the College who, to the knowledge of the Chief Executive Officer, or their delegate has sat on a panel of the Discipline Committee and has heard allegations against a Registrant at the selected premises will be assigned as an inspector for that premises.</p> <p>No inspector who, to the knowledge of the Chief Executive Officer, or their delegate has a conflict of interest with a Registrant , other health care practitioner or staff member who provide IVIT-related patient care at the premises will be assigned as an inspector for that premises.</p>
Conflict of Interest Criteria	<p>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.</p>
Setting a date and time	<p>The assigned inspector will contact the Designated Registrant to arrange a date and time for the inspection, which should occur within approximately 30 days. The</p>

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inspector will notify the College of the inspection date for each of the premises they are responsible for conducting.

For existing and Part II new premises inspections, the Designated Registrant shall make every effort to ensure that the inspection is conducted on a day when there are patients scheduled for IVIT treatments and compounding for IVIT will be performed.

Inspection	Inspector Authority	An inspector appointed by the College may enter and inspect a premises where administration of IVIT and/or compounding for IVIT are performed by a Registrant , at reasonable times, upon producing information identifying them as an inspector.
	Access to Premises	On the day of the inspection, the Designated Registrant will ensure that the inspector has access to all appropriate areas of the premises, and that all documentation relevant to the performance of procedures is made available, including but not limited to appointment books, accounts, reports, and patient records.
	Denial of Access	If an inspector is denied entry or access to a premises, all Registrants must cease to perform procedures at that premises until an inspection has taken place.
	Inspection components	<p>An inspection of a premises may include some or all of the following:</p> <ul style="list-style-type: none"> • a review of the physical layout, equipment, storage of drugs and substances being compounded and administered by IVIT, infection control and relevant emergency procedures in accordance with the Inspection Program Requirements, • a review of patient records and other documentation related to patient care, • observation of the administration of IVIT and/or compounding for IVIT procedures being performed in accordance with the Inspection Program Requirements and standards of practice, • a review of any reports made to the College regarding Type 1 and Type 2 occurrences at the premises, • a review of the Policies and Procedures Manual, • a review of any other material that is deemed relevant to the inspection.

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	Observation of a procedure	As part of an inspection, the inspector may directly observe a Registrant performing a procedure on a patient. Before the observation occurs, the inspector will identify themselves to the patient, explain the purpose of the observation, and inform the patient that the information obtained may be used in proceedings under Part IV of the <i>General Regulation</i> or any other proceeding under the Act, answer any questions that the patient asks and obtain the patient's written consent.
	Patient Consent	Written patient consent is necessary in order to allow the inspector to directly observe a treatment. Consent is obtained by the inspector so that the purpose for the observation can be fully explained to the patient. If a patient does not consent, direct observation of that patient's treatment cannot occur.
	Immediate Reporting of Unsafe Practices	If the inspector has reason to believe that there is a significant risk to patients due to the current compounding and/or IVIT practices at the premises they shall report this to the College immediately. The College will call an emergency meeting of the IC to determine if it is advisable to order the premises to stop performing procedures.
	Exit Interview	At the end of the inspection, the inspector will meet with the Designated Registrant to discuss the findings and anticipated content of the inspector's report, and to answer any questions the Designated Registrant may have. The inspector will also provide the Designated Registrant with the Post-inspection Questionnaire.
Post Inspection	Inspector's Report	Following the inspection, the inspector will complete the Inspector's Report form to include their observations, comments and recommendations regarding the inspection and will provide it to the College within approximately 14 days of the completion of the inspection.
	Inspection Outcome	After an inspection of a premises the IC will determine whether the outcome of the inspection is a pass, a pass with conditions, or a fail. The IC will utilize the Inspection Outcome Decision Pathway when determining the outcome. The IC will also consider the inspection results provided by the inspector, the Inspector's Report, any information or submissions

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made by any Registrant(s) practising at the premises and any other information that is directly relevant to the inspection.

Inspection Committee Report	Any Inspection Committee Report regarding an inspection of a premises where procedures are performed will include the outcome of the inspection as a pass, pass with conditions, or fail. Where a premises passed with conditions, the conditions will be stated. Where Inspection Program Requirements are partially met and do not warrant a condition being placed on the premises, the IC may make recommendations in the report.
Notice of Outcome	The College will provide the Designated Registrant with the Inspection Committee Report, within a reasonable time after the inspection is completed.
Registrant Submissions	A Registrant may make a submission to the College within 14 days of the date the Inspection Committee Report is received if the outcome is a pass with conditions or a fail.
Confirmation or Change of Decision	The IC may elect to re-inspect the premises after receiving a written submission, but will do one of the following within 60 days of receiving a submission, regarding the inspection outcome: <ol style="list-style-type: none"> 1. confirm its finding that the premises passed with conditions or failed, 2. make a report and find that the premises passed with conditions, 3. make a report and find that the premises passed the inspection.
Effective Date	A report that a premises has passed, passed with conditions or failed an inspection is effective on the date it was received in accordance with section 39 of the <i>Regulated Health Professions Act, 1991</i> by the Designated Registrant for the premises.
Restrictions on Performing Procedures	A Registrant shall not perform a procedure on a patient in a premises that has failed an inspection until: <ol style="list-style-type: none"> 1. the IC delivers a report indicating that following a subsequent inspection the premises passed or passed with conditions, or 2. the IC substitutes a finding that the premises passed or passed with conditions after considering the written submission, if any.

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A Registrant shall not perform a procedure on a patient in a premises that has passed with conditions except in accordance with the conditions set out in the report until:

1. the IC delivers a report indicating that the premises passed a subsequent inspection, or
2. the IC substitutes a finding that the premises passed the inspection, after considering the written submission, if any.

Follow-up /
Additional
Inspections

Premises that fail an inspection or pass with conditions may be subject to one or more further inspections within a reasonable time after the IC delivers its report. A follow-up inspection may occur at the request of a Registrant or Designated Registrant, or at any time at the discretion of the College, if it determines that it is necessary or advisable to do so.

The IC will 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.

A follow-up inspection may also be deemed to be necessary if the College has reason to believe that a premises is not complying with the conditions set out in the Inspection Committee Report.

Inspection
Program
Feedback

Registrant
Feedback

The Designated Registrant has the opportunity to provide feedback regarding the inspection process by completing the Post-inspection Questionnaire . The form should be returned to the College within 14 days of the inspection.

Inspector Feedback

Inspectors will be asked to provide feedback about the inspection process by completing and submitting the Inspector's Feedback form. Feedback will be requested annually prior to inspector training or at the time an inspector completes their term of service.

Use of Feedback

The College will review all Registrant and inspector feedback received and make any changes and improvements to the program and inspector training that are indicated. Information received regarding the

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inspectors will be communicated to the individual inspector if advisable.

Inspectors

Inspector Qualifications

Inspectors will be one of the following:

A naturopath who is registered with the College of Naturopaths of Ontario and has met the standards of practice for Intravenous Infusion Therapy and Prescribing,
OR

A member of another regulated health profession who is in good standing with their regulatory body and who is authorized, under the applicable legislation, to perform the controlled acts of compounding and administering a substance by intravenous injection.

Inspector Training

All Inspectors will be fully trained by the College on the Inspection Program and the inspection process.

Inspector Criteria - NDs

A Registrant will be eligible for appointment as an inspector if the individual:

- is registered in the General class OR in the Inactive class for less than 2 years,
- has met the standards of practice for IVIT and Prescribing,
- has actively performed IVIT and compounding for IVIT within the last 2 years,
- is not in default of payment of any fees or costs to the College,
- is not the subject of any disciplinary or incapacity proceeding,
- has not had a finding of professional misconduct, incompetence or incapacity against them in the preceding five years,
- is not currently nor has been a member of the College's staff at any time within the preceding one year,
- is not currently nor has been a member of the Council or a Committee of the College within the preceding one year.

Inspector Criteria - Other Regulated Health Care Professionals

A member of another regulated health profession will be eligible for appointment as an inspector if the member:

- is registered in the equivalent of the General class OR the Inactive class for less than 2 years,
- has the appropriate training in administering by intravenous injection and compounding,

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- has actively performed intravenous injections and compounding for intravenous injection within the last 2 years,
- is not the subject of any disciplinary, or incapacity proceeding,
- has not had a finding of professional misconduct, incompetence, or incapacity against them in the preceding five years,
- is not currently nor has been a member of the College's staff at any time within the preceding one year,
- is not currently nor has been a member of a Committee of the College within the preceding one year.

Inspector Appointment

The term of an inspector is approximately three years from the date they are appointed.

An inspector may request a deferral of their appointment or a leave of absence for up to one year, as long as they provide the IC with satisfactory reasons for the request.

When the inspector's three-year appointment nears its completion, the inspector may apply for re-appointment.

An individual who has served as an inspector for three consecutive terms is ineligible for re-appointment until a full year has passed since they last served as an inspector.

Inspector Application

An individual may apply or re-apply to the College to become an inspector by submitting a current CV/resume and a cover letter outlining the reasons(s) they are interested in being appointed or re-appointed as an inspector. The College may request that the individual submit any other relevant documentation.

Considerations

When appointing inspectors, the College will consider the following:

- need for inspectors,
- the individual's geographical location,
- any relevant experience,
- additional professional qualifications, expertise and/or specialty,
- languages spoken,
- communication skills, and
- interview evaluation.

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Inspector
Disqualification

An inspector will be discharged if they:

- breach one of the qualifications required to become an inspector as outlined in this policy,
- breach confidentiality of any information learned through an inspection,
- fail to properly or honestly meet the duties and responsibilities of the position for which they have been appointed.

Completion of
Appointment

An inspector will be considered to have completed their appointment and thanked for their services if they, having made arrangements with the College for the completion of any outstanding inspections, does any of the following:

- resigns in writing,
- completes their term of service and is not re-appointed, or
- completes three consecutive terms.

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