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

Definitions	Act	Means the <a href="#">Naturopathy Act, 2007</a> , as amended from time to time.
	Adverse Drug Reaction	Means 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. <sup>1</sup>
	By-laws	Means the <a href="#">by-laws</a> of the College approved by the Council under the authority of section 94 of the Code.
	Certificate of Registration	Means a document issued by the College, in the General class, emergency class or Inactive class, which demonstrates to the public that the holder is a registrant of the College, registered in the class set out on the certificate and identifies whether there are any terms, conditions or limitations (TCLs) placed on the certificate.
	Chief Executive Officer (CEO)	Means the individual appointed by the Council of the College pursuant to section 9(2) of the Code and who performs the duties assigned to the position of Registrar under the RHPA, the Code, the Act and the regulations made thereunder.
	Code	Means the <i>Health Professions Procedural Code</i> , which is Schedule 2 to the <a href="#">RHPA</a> .
	College	Means the College of Naturopaths of Ontario as established under the Act.
	Conflict of Interest	Means an instance where a reasonable person would conclude that a Committee member's or inspector's personal or financial interest 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, and direct or indirect.
	Council	Means the Council of the College as established pursuant to section 6 of the Act.

<sup>1</sup> Adapted from C.01.001 (1) of the Food and Drug Regulations (C.R.C., c.870) made under the Food and Drugs Act (Canada).

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Designated Registrant	Means a registrant <sup>2</sup> who is designated to deliver and accept information on behalf of a specified premises as per section 30 of the <a href="#">General Regulation</a> .
Existing Premises	Means a premises that was performing procedures prior to March 2, 2017 and registered as a premises between March 2, 2017 and May 1, 2017.
General Regulation	Means <a href="#">Ontario Regulation 168/15</a> made under the Act, as amended from time to time.
Inspector	Means a person appointed by the CEO or their delegate, to carry out an inspection under the <i>General Regulation</i> on behalf of the College.
Inspection Committee (IC)	Means the non-statutory committee of the College established pursuant to section 12.02 of the by-laws and GP06 – <a href="#">Committee Principles</a> of the Council’s governing policies.
New premises	Means a premises that was not performing procedures prior to March 2, 2017 and did not register as an existing premises between March 2, 2017 and May 1, 2017.
Premises	Means any clinic where a registrant performs or may perform a procedure.
Procedure	Means, <ul style="list-style-type: none"> <li>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</li> <li>ii. the administration of a customized therapeutic product described in (i) by intravenous injection to a patient by a registrant.<sup>3</sup></li> </ul>
RHPA	Means the <a href="#">Regulated Health Professions Act, 1991</a> , as amended from time to time.

<sup>2</sup> 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*.

<sup>3</sup> Procedure is defined in section 23(1) of the General Regulation made under the Act.

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General	Guiding Legislation	All aspects of the Inspection Program will be managed in accordance with the RHPA, the Act, the Code, the <i>General Regulation</i> , and the College by-laws.
	Confidentiality	Committee members and inspectors have a general statutory duty of confidentiality, as set out in section 36 of the RHPA, which provides that all representatives of the College shall keep confidential all information that comes to their knowledge in the course of their duties, and shall not communicate any information to any person except to the extent the information is available to the public under the RHPA, in connection with the administration of the Act, or in certain other narrow, specified circumstances.
	Participation	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. <sup>4</sup>
Inspection Committee	Composition	The Committee will be composed in accordance with the College by-laws and the terms of reference.
	Quorum	Quorum will be determined in accordance with section 12.06 of the by-laws of the College and the <a href="#">Inspection Committee terms of reference</a> .
	Per diems and expenses	Committee members who are not Public members appointed by the Lieutenant Governor in Council are entitled to a per diem and reimbursement of authorized expenses as outlined in the Council's governance policy <a href="#">GP18 – Per Diems and Expenses</a> .
	Responsibilities	The Committee will carry out its responsibilities as outlined in Part IV of the General Regulation and the terms of reference. The Committee will also: <ul style="list-style-type: none"> <li>• review all Type 1 occurrence reports and determine if further action is required,</li> <li>• review a summary of the Type 2 occurrence reports,</li> <li>• review and decide upon requests made to defer an inspection.</li> </ul>
Designated Registrant	Qualifications	All premises in which procedures are performed must have a Designated Registrant assigned at all times. The Designated Registrant must be a registrant who has met the standard of practice for Intravenous Infusion Therapy and holds a General certificate of registration.

<sup>4</sup> Pursuant to section 26(1) of the General Regulation made under the Act.

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Responsibilities

The Designated Registrant is the contact person for a premises and is responsible for:

- communicating with the College regarding the Inspection Program,
- the payment of fees regarding the premises and any inspections thereof,
- informing the College immediately when a different registrant is taking on the role of the Designated Registrant for the premises,
- informing the College within 30 days of any changes regarding:
  - registrants who perform procedures,
  - new procedures being performed at the premises, and
  - procedures no longer being performed at the premises,
- submitting the Type 2 occurrence annual report,
- receiving the Inspection Committee report with the inspection outcome,
- providing copies of the Inspection Committee report to registrants who perform or may perform procedures at the premises when the outcome is a pass with conditions or a fail,
- making a submission in response to an outcome of a fail or pass with conditions, and
- ensuring that all staff who perform procedures at the premises meet the responsibilities and requirements outlined in the College's Inspection Program Requirements, the Inspection Program Handbook, and Part IV of the *General Regulation*.

Registering a New Premises      New Location

The Designated Registrant for a premises where registrants are intending to perform procedures must provide written notification to the College by completing the Registering an IVIT Premises form and paying the premises registration fee.

Moving

A premises that is authorized to perform procedures and moves to a new location must register as a new premises by completing the Registering an IVIT Premises form and paying the premises registration fee.

Resumption of Procedures at a Premises

A premises that was previously authorized to perform procedures and subsequently ceased to perform procedures, is considered to be a new premises if they intend to re-open or resume performing procedures and must register as a new premises by completing the

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Registering an IVIT Premises form and paying the premises registration fee.

Frequency and Timelines of Inspections

5-year Inspections

All premises where a registrant performs or may perform a procedure are subject to inspection by the College once every 5 years, following the initial inspection for an existing premises or Part II of a new premises.

Ordered Inspections

Pursuant to section 32 of the *General Regulation* the College may inspect a premises if it is of the opinion that it is necessary or advisable to do so.

New Premises – Part I

New premises in which registrants are intending to perform procedures will undergo Part I of the new premises inspection within 180 days of the College receiving the Registering an IVIT Premises form.

The Designated Registrant will be required to withdraw their request to register a new IVIT premises if they are unable to schedule an inspection prior to the 180-day deadline.

No premises shall perform procedures prior to a New Premises – Part I inspection is completed and receives an outcome of a pass or a pass with conditions.

New Premises – Part II

New premises will undergo Part II of the new premises inspection approximately 6 months following the completion of the Part I inspection.

Inspection Fees

Payment of Fees

All premises that are subject to an inspection must pay the inspection fees to the College as per section 18.05 and Schedule 3 of the by-laws.

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

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

Invoicing of fees

For all 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.

For a new premises, the inspection of a new premises fee as stated in Schedule 3 of the by-laws will be invoiced upon notification to the Designated Registrant of the assigned inspector for the Part I inspection.

Refunds/Waived fees

The premises registration fee will not be refunded to a premises that withdraws its registration as a new

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premises.

Inspection fees that have been invoiced and/or paid will not be waived or refunded to a premises that submits a Cease to Perform IVIT form after the premises has undergone the inspection.

The inspection fee will be waived for a premises that submits a Cease to Perform IVIT form more than 7 days prior to the scheduled date of the inspection.

If a premises has paid the inspection fee and then submits a Cease to Perform IVIT form more than 7 days prior to the schedule date of the inspection, the inspection fee will be refunded.

Non-payment of fees

If the fee is not paid within the required timeframe the administrative fee for notices as stated in Schedule 3 of by-laws may be applied.

As outlined in section 24 of the Code, if payment is not received, the Designated Registrant's registration may be suspended for failure to pay fees.

Type 1 and Type 2 Occurrences

Reporting

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

Type 1 Occurrence Report Requirements

A Type 1 Report must be made no later than 24 hours after the registrant learns of the occurrence.

All Type 1 occurrence reports must include the following information:

- i. which Type 1 occurrence happened,
- 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. Further action may include, but is not limited to:

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- a request for additional information from the reporting registrant,
- ordering of an inspection of the premises,
- inform the Regulatory Affairs Department that it has grounds to believe a registrant may have committed an act of professional misconduct or may be incompetent or incapacitated.

Type 2 Occurrence Reporting Type 2 occurrence reports are to be submitted, by the Designated Registrant, 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.

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 Notification of Selection The Designated Registrant will receive written notification that the premises has been selected for an inspection. Notification will occur via email as well as fax or mail.

Notification of a 5-year inspection The Designated Registrant will be notified of the 5-year inspection at least 4 months before the 5-year anniversary of the previous inspection.

Notification of a New Premises Part I Inspection The Designated Registrant will be notified of the Part I inspection as soon as is practicable after receiving the Registering an IVIT Premises form and the premises registration fee to ensure ample time is allowed to complete the inspection within 180 days of receipt of the form.

Deferral Requests The Designated Registrant for a premises that is selected for an inspection and where they are the only ND who provides IVIT in the premises, may seek a deferral if they are on parental leave, are on a leave-of-absence, are seriously ill, or if there are other extenuating circumstances.

The request may be accompanied by supporting documentation verifying the circumstances for the deferral request.

All deferral requests will be reviewed by the IC on a case by case basis. Deferrals are granted based on the validity and severity of the situation that may delay or prevent the Designated Registrant from submitting the necessary documents or attending the inspection.

Required Forms Submitted by the When a premises is notified that it has been selected for an inspection, the College will provide the

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Designated Registrant

Designated Registrant with the Pre-inspection Information (Part II and 5-year inspections) and Registrant Declaration of a Conflict of Interest forms (all inspections) that must be completed and returned to the College within, at least 14 days.

Assignment of an Inspector

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.

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.

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.

Setting a date and time

The inspector will contact the Designated Registrant within approximately 30 days after the Designated Registrant is notified of the assigned inspector, to arrange a date and time for the inspection. The inspector will notify the College of the inspection date for each of the premises they are responsible for inspecting.

For 5-year 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. If a patient is not available, the Designated Registrant will arrange for a mock patient to be used to demonstrate the administration of IVIT by performing all aspects of the procedure except the insertion of the needle.

Inspections

Inspection Authority

All inspections will be conducted in accordance with the authorities outlined in Part IV of the *General Regulation*.

Components

All components of an inspection are contained in the Inspection Program Requirements for Part I and Part II new premises inspections, and 5-year inspections. Inspection requirements address the following:

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- the physical environment,
- equipment and storage of drugs and substances used when compounding and administering by IVIT,
- infection control,
- emergency preparedness,
- record keeping and charting,
- observation of the administration of IVIT and/or compounding for IVIT,
- reporting Type 1 and Type 2 occurrences,
- delegation,
- documented policies and procedures, and
- quality management.

Immediate Reporting of Unsafe Practices

If an inspector has reason to believe that there is a significant risk of harm to patients due to the current compounding and/or IVIT practices at the premises they shall report this to the College immediately. The Chair will call an emergency meeting of the IC to consider whether to order the premises to cease performing procedures.

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 checklists provided by the inspector, the Inspector's Report, any information or submissions made by any registrant(s) practising at the premises and any other information that is directly relevant to the inspection.

Inspection Committee Report

The Inspection Committee Report 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.

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Notice of Outcome	The College will provide the Designated Registrant with the Inspection Committee Report by email, within approximately 10 days following the IC meeting.
Registrant Submissions	As outlined in section 33(9) of the <i>General Regulation</i> 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	As outlined in section 33(10) of the <i>General Regulation</i> , the IC may or may not 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: <ul style="list-style-type: none"> <li>confirm its finding that the premises passed with conditions or failed,</li> <li>make a report and find that the premises passed with conditions,</li> <li>make a report and find that the premises passed the inspection.</li> </ul>
Effective Date	As outlined in section 33(5) of the <i>General Regulation</i> 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	As outlined in section 33(7) of the <i>General Regulation</i> a registrant shall not perform a procedure on a patient in a premises that has failed an inspection until: <ul style="list-style-type: none"> <li>the IC delivers a report indicating that following a subsequent inspection the premises passed or passed with conditions, or</li> <li>the IC substitutes a finding that the premises passed or passed with conditions after considering the written submission, if any.</li> </ul> <p>As outlined in section 33(8) of the <i>General Regulation</i> 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:</p> <ul style="list-style-type: none"> <li>the IC delivers a report indicating that the premises passed a subsequent inspection, or</li> <li>the IC substitutes a finding that the premises passed the inspection, after considering the written submission, if any.</li> </ul>

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Follow-up /  
Additional  
Inspections

As outlined in section 33(11) of the *General Regulation*, a premises that fails an inspection or passes with conditions may be subject to one or more subsequent inspections within a reasonable time after the IC delivers its report. A subsequent inspection may occur at the request of a registrant or the 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 subsequent 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, a subsequent inspection may be required in order to ensure the issues have been rectified prior to the premise being allowed to resume performing procedures.

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

The cost of a subsequent inspection or an inspection ordered by the IC is charged to the Designated Registrant in accordance with Schedule 3 of the by-laws.

Inspection  
Program  
Feedback

Registrant  
Feedback

The Designated Registrant has the opportunity to provide feedback regarding the inspection process by completing the Post-inspection Questionnaire.

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 periodically 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 inspectors will be communicated to the individual inspector if advisable.

Inspectors

Inspector's Per  
Diem and  
Expenses

Inspectors are entitled to a per diem of \$300 for each inspection conducted, this includes the time spent in inspection preparation, conducting the inspection and drafting the Inspector's Report. Reimbursement for

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expenses will be in accordance with GP18 - Per Diems and Expenses.

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

Inspector Eligibility - 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 two years,
- has met the standards of practice for IVIT and Prescribing,
- has actively performed IVIT and compounding for IVIT within the last two years,
- is not in default of payment of any fees prescribed by the by-laws or any fine or order for costs to the College imposed by a College committee or court of law,
- is not in default in completing and returning any form required by 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,
- has not been disqualified from Council or a committee of the College in the previous three years,
- is not currently nor has been a member of the College's staff at any time within the preceding one year, and
- is not currently nor has been a member of the College's Council or Inspection Committee within the preceding one year.

Inspector Eligibility - 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 two years,
- has the appropriate training in administering by intravenous injection and compounding,
- has actively performed intravenous injections and compounding for intravenous injection within the last two years,
- is not the subject of any disciplinary or incapacity proceeding,

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- 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 Inspection Committee of the College within the preceding one year.

Inspector Application

An individual may apply or re-apply to the College to become an inspector by completing the forms and submitting the documents as outlined in the Volunteer Program.

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, and
- communication skills.

Inspector Appointment

All inspectors will be appointed by the College's CEO or their delegate.

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, do any of the following:

- fail to continue to meet the eligibility criteria,
- resign in writing, or
- is relieved of their services as an inspector.

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