Policy on individual(s) accompanying a health products inspector

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Table of Contents

Policy on individual(s) accompanying a health products inspector

1.0 Purpose

The purpose of this policy is to inform stakeholders of subsection 23(7) of *Food and Drugs Act* (Act), which authorizes designated inspectors to be accompanied by any other individual the inspector believes is necessary to help them exercise their powers or perform their duties or functions under section 23 of the Act.

This policy explains:

- the general circumstances where inspectors might be accompanied by one or more individuals to help them exercise their powers, or perform their duties or functions under the Act
- the rights and responsibilities of regulated parties
- the consequences for parties that obstruct, hinder or provide false information, or fail to provide reasonable assistance to an inspector, including when they are accompanied by an individual under subsection 23(7) of the Act

2.0 Background

This policy is an administrative document. If there is inconsistency or conflict between the Act or regulations and this policy, the Act or regulations take precedence.

The Act and regulations establish a regulatory framework to help protect the health and safety of consumers using health products, which are regulated under the Act. It also helps to prevent deception in relation to these products.

Health Canada's Regulatory Operations and Enforcement Branch (ROEB) has two directorates that are responsible for the compliance and enforcement of health products. These are the Health Product Compliance Directorate (HPCD) and the Medical Devices and Clinical Compliance Directorate (MDCCD). HPCD and MDCCD staff monitor or verify that health products comply with the Act and its regulations.

The Minister of Health designates inspectors to administer and enforce the Act. For the purpose related to verifying or preventing non-compliance with the Act or the regulations, designated inspectors are given powers and authorities. Some of those powers or authorities are set out in section 23 of the Act,

and include the authority of an inspector to be accompanied by any other individual that the inspector believes is necessary to help them exercise their powers or perform their duties or functions under this section.

Not every person accompanying an inspector will do so under the authority of subsection 23(7) of the Act. In some cases, an individual may accompany a designated health products inspector for purposes other than to help the inspector exercise their powers or perform their duties or functions, with the consent of the regulated party who is being inspected. As an example, a new inspector may observe for training purposes.

3.0 Responsibilities

Inspectors designated under subsection 22(1) of the Act are responsible for:

- identifying the appropriate individual(s) they believe is (are) necessary to help them exercise their powers or perform their duties or functions under section 23 of the Act
- if advance notice of the inspection is given, and as appropriate, advising the regulated party that the inspector will be accompanied by an individual(s) they believe necessary to help them exercise their powers or perform their duties or functions under section 23 of the Act
- providing the individual(s) accompanying them with any necessary briefing and/or information resources required to prepare for the inspection
- communicating to the person accompanying any pertinent responsibilities regarding sensitive information which may be encountered during the inspection
- ensuring that the individual(s) who accompany them remain under their supervision and direction throughout their time on site
- reporting to their supervisor or manager if the regulated party obstructs, hinders, provides false or misleading statements or refuses to provide all reasonable assistance

Individuals accompanying inspectors under subsection 23(7) of the Act are responsible for:

- identifying themselves and providing their identification or credentials to the inspector, and to the person in charge of the place being inspected, upon request
- taking necessary steps to protect their own health and safety during the inspection
- minimizing the risk to protected, classified and confidential information
- following the direction of the inspector under whose authority they have entered, and adhering to the requirements of any contract into which they have entered with Health Canada
- respecting and adhering to any applicable regulatory requirements, policies and/or procedures as directed in regards to the inspection, and as consistent with their role in assisting the inspector

Parties regulated under the Act must:

- understand their legal obligations
- comply with the applicable legislative provisions

- be prepared to be inspected at any reasonable time
- identify the people who are required to provide information to the inspector, and ensure that they are available when an inspector is verifying compliance
- provide all reasonable assistance to the inspector
    - includes providing information that establishes their identity to the inspector's satisfaction

Under subsection 24(1), no person may obstruct, hinder or knowingly make false or misleading statements, either orally or in writing, to an inspector. These provisions require a person to provide an inspector, with any information that an inspector may reasonably require.

Failure to comply with these provisions is an offence.

4.0 Scope

This policy applies to inspections, including activities undertaken to verify compliance, either in person, as authorized by subsection 23(1), or remotely, by a means of telecommunication as authorized by subsection 23(3) the Act. Inspections, including compliance verification activities, may take place unannounced, or may be scheduled in advance with the regulated party.

Inspectors have the authority to verify compliance or prevent non-compliance with the Act and its regulations for a range of health products, including:

- medical devices
- human drugs (pharmaceuticals, biologicals, radiopharmaceuticals)
- natural health products
- blood and blood components for transfusion or for the use in the manufacture of a drug for human use
- cell, tissues and organs for transplantation
- veterinary drugs and veterinary health products

The authority under subsection 23(7) of the Act that provides for an individual to accompany an inspector applies only to individuals that an inspector believes are necessary to help them exercise their powers or perform their duties or functions under the Act. This policy does not apply to all individuals who may accompany inspectors designated under the Act. For example, other regulators or peace officers, may be present at an inspection under their own authorities.

5.0 Policy statement

Any person whose activities are subject to the Act and its regulations must comply with the legislation. When carrying out their work, an inspector may reasonably believe it is necessary to be accompanied by one or more subject matter experts, logistical support, or others, to help the inspector exercise their powers or perform their duties or functions under the Act. This determination by the inspector may take place in advance of, or during, the course of the inspection. An inspector may or may not notify the regulated party in advance that they will be accompanied by an individual to help them exercise their powers or perform their duties or functions.

Individuals accompanying inspectors do not have the authorities of inspectors under the Act as a result of their presence at an inspection pursuant to subsection 23(7). However, the authority for inspectors to be accompanied by an individual(s) to help them exercise their powers or perform their duties or functions is essential to the effective administration of the Act.

Failure to provide all reasonable assistance to an inspector is a serious offence. Health Canada may take action, using measures outlined in the *Compliance and enforcement policy for health products* (POL-0001).

6.0 Powers of inspectors

Under the Act, the inspector has certain powers to verify compliance with the Act and regulations, as well as to prevent non-compliance.

6.1. Power to enter a place (subsection 23(1))

An inspector, and any individual(s) accompanying them under the authority of subsection 23(7) of the Act, may enter any place, including a conveyance, in which the inspector has reasonable grounds to believe that:

- an activity that may be regulated under this Act is being conducted
- any article to which this Act or the regulations apply is located, or
- an activity could be conducted under an authorization, including a licence, for which an application is under consideration by the Minister

Inspectors may enter places that meet the criteria described in subsection 23(1) of the Act at any reasonable time. While the facts will establish what is reasonable, in most cases, entry during the normal working hours of the place being entered is considered reasonable. Consent to enter is not required for entry into a place, unless the place being entered is a dwelling-house.

6.2. Power to conduct a remote entry (subsection 23(3))

An inspector, and any individual accompanying them under the authority of subsection 23(7) of the Act, can also enter a place as described in *Accessing the Premises of a Regulated Party Remotely to Verify Compliance (POL-0138)* by means of telecommunication.

6.3. Power to enter private property (subsection 23(8))

An inspector, and any individual(s) accompanying them under the authority of subsection 23(7) of the Act, may enter and pass through private property, other than a dwelling-house on that property, in order to gain entry into the place to be inspected.

6.4. Consent to enter a dwelling-house (subsection 23(9))

When a regulated party conducts business in their home, an inspector and any individual(s) accompanying them may enter the dwelling-house only if the occupant consents, or if there is a warrant issued under subsection 23(10).

The inspector must have reasonable grounds to believe that one of the paragraphs in subsection 23(1) applies.

The inspector will use a form to obtain consent from the occupant in advance of entering to conduct the inspection. This form includes details of the inspector's authorities once the inspector enters the dwelling-house.

6.5. Other powers (subsection 23(2))

Inspectors may exercise other powers to verify compliance or prevent non-compliance once they have entered a place physically or remotely. Under the Act, their authorities include the power to do the following:

- take photographs and make recordings or sketches
- examine any article
- test any article
- take samples of any food, drug, cosmetic, device or anything used for an activity regulated under the Act
- open and examine any container, receptacle or package

- examine, copy, make copies of or reproduce books, documents, reports, test data, shipping bills, bills of lading, labels, advertising and promotional material, or other records, including electronic data
- print, copy or extract data from any computer system
- use any computer system or telecommunication system at the place
- remove anything for examination, conducting tests or taking samples
- seize and detain any article

These powers apply only to designated inspectors, and not to individual(s) who accompany them. However, the inspector may rely upon the assistance of an individual(s) accompanying them in order to exercise their powers or perform their duties.

7.0 Decision to have an individual accompany an inspector

Examples of when an inspector may believe it is necessary to have an individual(s) accompany them include, but are not limited to, the following situations:

- the skills, knowledge, experience and qualifications of the individual(s) accompanying are needed to conduct the inspection, and/or specialized knowledge possessed by a subject matter expert is required, including, for example:
    - a molecular biologist
    - a laboratory analyst
    - a data integrity expert
    - a software engineer
    - any other scientific, medical, or technical expert
- there are aspects of the inspection which an inspector believes will necessitate logistical support (e.g. movers)
- the anticipated cooperation of the regulated party cannot be adequately assured, and the inspector anticipates needing assistance (e.g. a locksmith)

The inspector will decide the extent to which the accompanying individual's assistance is necessary, and for how long the individual(s) will remain in the place for that purpose.

7.1. Qualifications of the individual(s) accompanying

Individuals accompanying an inspector to assist them in their duties will be appropriately qualified and/or licensed, as required, with respect to their role(s). All individuals accompanying an inspector

under subsection 23(7) will produce appropriate identification upon request of the person in charge of the place being entered.

7.2. Confidential information and privacy concerns

Articles (including, but not limited to, records, products and equipment) to which the Act or its associated regulations apply are subject to inspection. When an inspector believes, on reasonable grounds, that records include relevant information, the inspector is authorized to view or examine those articles to verify compliance or prevent non-compliance. An individual(s) accompanying the inspector may also look at certain articles related to their field of expertise, as directed by the inspector they are accompanying, in order to help the inspector exercise their powers or perform their duties or functions.

Regulated entities have a reduced expectation of privacy than that of individuals. When a person undertakes activities regulated under legislation, those persons are subject to inspection for compliance with all applicable legislation. However, the inspector and any individual(s) accompanying them will take steps to safeguard protected, classified and confidential information. Inspectors will communicate the importance of proper handling of sensitive information and ensure that individuals accompanying them on inspection understand and follow their direction.

More information on the legislative provisions related to records accessed and obtained by inspectors during compliance and enforcement activities is available in the *Policy on Collection and retention of records related to health product compliance and enforcement* (POL-0140).

7.3. Safety of the individual(s) accompanying an inspector

Inspections under the Act may occur in places that are inherently hazardous. In advance of entry, the inspector will attempt to work with the regulated party, as appropriate, to identify any potential hazards to the inspector and/or any individual(s) accompanying them. Such hazards may include, but are not limited to, the following:

- warehouse areas with falling hazards or risks from equipment (e.g. forklifts)
- manufacturing, clinical, or laboratory areas with chemical or biological hazards
- retail environments with human hazards
- confined areas with air quality hazards

Regulated parties are responsible for providing all information requested or reasonably expected by an inspector with the goal of maintaining the health and safety of an inspector and any individual(s) accompanying them, during and resulting from the inspection. Regulated parties are also responsible

for ensuring that inspectors and any individual(s) accompanying them are not subjected to unreasonable or foreseeable hazards during the inspection of their premises.

Inspectors and any individual(s) accompanying them are responsible for cooperating with the regulated party in terms of facility safety requirements, and taking necessary and reasonable steps to protect their own health and safety, for example, by using personal protective equipment. Health Canada inspectors and individuals accompanying them under the authority of subsection 23(7) will conduct the inspection in a safe manner that does not put either themselves or the regulated party in a position where their safety is at an increased risk.

More information can be found in the Guide to Health Canada inspections.

7.4. Following an inspection

Following an inspection, an individual(s) who accompanied an inspector to help them in their duties may be required to complete additional tasks to help complete the case file, including participating in inspection exit meetings, or subsequent communications with the company following a physical or remote entry as it relates to their area of expertise.

7.5. Obstructing, providing false information or failing to provide assistance

Obstruction, hindering, knowingly lying, or failing to provide all reasonable assistance to an inspector who is carrying out their duties or functions are offences under the Act and regulations and will not be tolerated. Compliance and enforcement actions that may be taken are outlined in the *Compliance and enforcement policy for health products* (POL-0001).

The inspection provisions in the Act are designed to protect consumers who are vulnerable to risks posed by health products, and their advertising. It is a violation of subsection 24(1) to prevent an inspector from inspecting or to make false or misleading statements, orally or in writing.

Depending on the classification and type of the health product involved and the election of the prosecutor to proceed summarily or on indictment, a violation may result in prosecution. If convicted, a person can be fined or be imprisoned. Subsection 23(13) puts a duty on the owner or person in charge and any person found in a place entered (even remotely) by an inspector to provide:

- reasonable assistance
- required information

Appendix A – Glossary

Acronyms

HPCD: Health Products Compliance Directorate

MDCCD: Medical Devices and Clinical Compliance Directorate

ROEB: Regulatory Operations and Enforcement Branch

Terms

Compliance: The state of conformity of a regulated party (including a corporation, organization, individual or other legal entity) or a product with a legislative or regulatory requirement.

Compliance verification: Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act and its regulations. This includes actions such as gathering information either off-site or through on-site inspections.

Consent: Consent given by an individual that is the result of free choice. The statement is obtained without compulsion or coercion.

Dwelling-house: Defined in the *Criminal Code of Canada* as the whole or any part of a building or structure that is kept or occupied as a permanent or temporary residence. Includes:

- a building within the curtilage of a dwelling-house and that is connected to it by a doorway or a covered and enclosed passageway
- a unit that is designed to be mobile and to be used as a permanent or temporary residence and that is being used as such a residence

Enforcement: Actions that may be taken to compel or induce compliance to mitigate the risk identified by non-compliance with the Act and its associated regulations.

Health product: Includes any product regulated under the Act and falling within the mandate of the MDCCD and HPCD, such as:

- pharmaceutical, biological and radiopharmaceutical drugs for human use
- veterinary drugs and veterinary health products
- medical devices
- natural health products

- blood and blood components for transfusion or for use in the manufacture of a drug for human use
- cells, tissues and organs for transplantation

Inspection: Monitoring and assessment against the applicable requirements of the Act and its regulations. Inspections are routinely conducted based on risk in order to assess compliance.

Inspector: Any person designated as an inspector under section 22 of the Act.

Person: Defined in section 2 of the Act to mean an individual or an organization as defined in section 2 of the *Criminal Code of Canada*.

Reasonable grounds to believe: Beliefs based on compelling and credible information such as knowledge, experience, expert advice or other information from a reliable source. Vague suspicion, subjective opinion or speculations are not sufficient to meet the requirement of having reasonable grounds of belief.

Remote entry: The entry of a place by an inspector by means of telecommunication.

Telecommunications: Defined in the *Interpretation Act* as the emission, transmission or reception of signs, signals, writing, images, sounds or intelligence of any nature by any wire, cable, radio, optical or other electromagnetic system, or by any similar technical system.

Appendix B -- References

Laws and Regulations

Criminal Code of Canada
laws-lois.justice.gc.ca/eng/acts/C-46/

Food and Drugs Act
laws-lois.justice.gc.ca/eng/acts/f-27/

Interpretation Act
https://laws-lois.justice.gc.ca/eng/acts/i-21/page-1.html

Other related documents

A guide to Health Canada inspections

https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/guide-inspections.html

Assessing the premises of a regulated party remotely to verify compliance (POL-0138)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-accessing-premises-regulated-party-remotely-verify-compliance.html

Compliance and enforcement policy for health products (POL-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

Policy on collection and retention of records related to health product compliance and enforcement (POL-0140)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-collection-retention-records-health-product-compliance-enforcement.html