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Policy on accessing the premises of a regulated party remotely to verify compliance



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For more information, please contact:

Health Canada
Address Locator 0900C2, Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
Email: hc.publications-publications.sc@canada.ca

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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.

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1.0 Purpose

The purpose of this policy is to inform stakeholders of the legislative provisions for accessing a regulated party's place remotely. Entering a place remotely (using telecommunication) is known as "remote entry."

This policy explains:

- remote entry
- the general conditions for conducting a remote entry
- the rights and responsibilities of parties
- the consequences for parties that obstruct, hinder, provide false information, or fail to provide reasonable assistance during a remote entry

2.0 Background

This policy is an administrative document. It is intended to help stakeholders comply with the [*Food and Drugs Act*](#) (the Act) and its regulations, as well as applicable administrative policies. 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 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 compliance and enforcement activities related to 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 are in compliance with the Act and its regulations.

Inspectors are designated by the Minister of Health to administer and enforce the Act. They have the authority to enter certain places. This includes the power to access a premise remotely to verify compliance or prevent non-compliance. Not every telecommunication contact by an inspector is considered an entry under subsection 23(3) of the Act. Inspectors and other departmental staff may contact a person without conducting a remote entry. However, when an inspector, for the purpose of subsection 23(1), remotely accesses a place that is not accessible to the public, they will ensure the owner or person in charge has been informed. This follows subsection 23(4).

Examples of telecommunication contact that are not a remote entry are when an inspector:

- asks a regulated party in an email to provide documented procedures required by the regulations so they may assess for compliance
- conducts recall effectiveness checks by phone to verify that those affected by a recall have received the recall information and are aware of the action(s) they need to take

3.0 Responsibilities

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

- decide whether to conduct a remote entry
 - they must have reasonable grounds to believe that the remote access meets the threshold, as set out in subsection 23(1)
- confirm that the regulated party has the technological capability for remote access
- inform the owner or person in charge of the place that a remote entry will take place
- get consent from the occupant to enter if the place is a dwelling-house
- provide detailed instructions to the regulated party on how to connect to the telecommunication platform, as well as use the tools provided within the application
- arrange for remote access
- ensure that remote access takes only as long as is necessary to verify compliance
- report to their supervisor or manager if the regulated party obstructs, hinders, provides false or misleading statements or refuses to provide all reasonable assistance
- ensures information collected from the regulated party is safely controlled and stored

Parties regulated under the Act must:

- understand their legal obligations
- comply with the 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 they are present for the remote entry
- provide video capability during the remote entry if applicable or available and when required by the inspector
- provide all reasonable assistance to the inspector
 - includes information that establishes their identity to the inspector's satisfaction

Under subsection 24(1), a regulated party may not obstruct, hinder or knowingly make false or misleading statements, either orally or in writing, to an inspector.

Failure to comply with these provisions is an offence.

4.0 Scope

This policy applies to inspections, including activities undertaken to verify compliance, such as accessing a place remotely. Remote entries using telecommunication are authorized by subsection 23(3) of the Act.

Designated 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

Remote entries may only be conducted with the knowledge of the owner or person in charge of the place. Other types of telecommunication contact by inspectors or other staff at Health Canada are not considered an entry under this authority.

5.0 Policy Statement

Any person whose activities are subject to the Act and its regulations must comply with the legislation. Inspectors assess compliance using several methods, such as entering a place remotely using telecommunication where appropriate. Telecommunication systems may include telephone, video calling or other web-based systems that fall within the definition of telecommunications as defined in the [Interpretation Act](#).

Once the inspector has informed the owner or person in charge of the remote entry, all inspector authorities provided for in subsection 23(2) of the Act are available to the inspector.

The authority to enter certain places using telecommunications is essential for the protection of consumers. It is used to help reduce the risk to their health and safety. Failure to provide all reasonable assistance to an inspector conducting a remote entry 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 Remote Entry

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

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

An inspector may enter any place, including a conveyance, in which they have 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 may dictate what is reasonable, in most cases, the normal working hours of the place being entered is considered reasonable. Consent to enter is not required for entry into a place located in Canada, unless the place being entered is a dwelling-house.

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

An inspector is considered to have entered a place when they access it remotely by a means of telecommunication.

For example, inspectors may verify that seized or quarantined products are in place by viewing the products through a video link. They may examine:

- material not open to the public to verify compliance or
- records or products (such as diagnostic software) being maintained exclusively within a computing cloud

Requirement for knowledge and limit duration (subsection 23(4))

There are restrictions to an inspector's power to access a place remotely that is not open to the public.

Inspectors may only do so:

- with the knowledge of the owner or person in charge of the place
- for the length of time required to verify compliance or prevent non-compliance

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

When a regulated party conducts business in their home, an inspector may enter the dwelling-house only if the occupant consents or there is a warrant (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 the inspection. This form includes details of the inspector's authorities once the inspector enters the dwelling-house.

This consent is separate from the knowledge requirement that is required by subsection 23(4) of the Act.

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 authority of the Act, they may:

- take photographs and make recordings or sketches
- examine any article
- test any article
- 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
- examine electronic data
- print, copy or extract data from any computer system

Decision to conduct a remote entry

The decision to conduct a remote entry follows our [*Compliance and enforcement policy for health products \(POL-0001\)*](#).

In making the decision to conduct a remote entry, the inspector will consider a number of factors, including:

- the need to protect everyone’s health and safety (for example, during an emergency or pandemic)
- the compliance history of the regulated party
- the inherent risk posed by the activities conducted, the types of products and the market distribution
- whether compliance with the Act and associated regulations can be verified through a remote entry
- whether the location of the regulated party makes it more efficient to use the remote entry method to verify compliance

Inspectors will use their discretion to determine whether an inspection will include both a remote entry and an on-site visit.

Knowledge of a remote entry

An inspector will ensure that the owner or person in charge of the place knows that a remote entry is taking place.

When using conferencing applications, such as web, video or teleconferencing, an inspector will provide written notice in advance. This notice will include:

- information on how to connect
- date and time for the remote entry
- how long the remote entry is expected to last
- name(s) of the inspector(s) who will be doing the remote entry
- name(s) of anyone else with the inspector(s)

When inspectors conduct a remote entry by telephone, the owner or person in charge may be informed verbally. In some cases, they may find out at the beginning of the phone call.

Once entered

When the inspector enters a place, they will:

- identify themselves as an inspector and upon request show appropriate identification
- verify compliance with the Act and regulations, including any applicable standards, and any licences, registrations or other authorizations, based on the facts collected through observation, measurement, testing or other means
 - if the person is in compliance, no further action will be taken
 - a written summary of non-compliance issues will be provided to the regulated party; enforcement actions are taken following the [Compliance and enforcement policy for health products \(POL-0001\)](#)

- the regulated party will be required to respond to the non-compliance(s)

Duration of the remote entry

The duration of the remote entry will be only as long as necessary for the inspector to prevent non-compliance or to verify compliance. The duration will depend on a variety of factors, including how many regulated activities are being inspected and how many health products are impacted. Regulated parties that cooperate can help to shorten the length of time for the remote entry review.

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 will not be tolerated. Further 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 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 could 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 information gathering via either off-site or on-site visits.

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* 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
- 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 to assess compliance.

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

Investigation: Actions taken to gather evidence to support case referral for potential prosecution regarding specific violations of the *Food and Drugs Act* and its associated regulations. This includes activities carried out under the *Criminal Code*, such as taking witness statements and executing search warrants.

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

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

laws-lois.justice.gc.ca/eng/acts/i-21/index.html

Policies

POL-0001: Compliance and enforcement policy for health products

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>