POL-0011: Good manufacturing practices inspection policy for drug establishments

April 7, 2022

Canada

Health Canada Santé Canada

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Table of contents

The following legend shows the alerts used in this document and the way they are intended to be used.

Key or cautionary information.

Supplementary information like quotes and legal references.

1. Purpose

Establishments need a drug establishment license (DEL) to be authorized to conduct the following licensable activities: fabricate, package/label, test, import, distribute, or wholesale of drugs. Health Canada inspects these sites to verify requirements for good manufacturing practices (GMP) are met before DEL issuance. This helps ensure that safety and quality standards are met by those selling drugs to Canadians.

This policy describes the inspection strategy for GMP inspections of:

- Canadian buildings that require a DEL
- foreign buildings that must be authorized on a DEL

It also describes the inspection process we use to assess whether the activities performed in a building comply with the:

- *Food and Drugs Act* (the Act)
- *Food and Drug Regulations* (the Regulations)

Health Canada's authority to inspect buildings in Canada comes from section 23 of the Act. Health Canada inspectors are designated under subsection 22(1) of the Act.

The main objectives of Health Canada's inspection strategy are to:

1. minimize the health risks throughout the drug supply chain
2. assess, through inspections, the compliance of those establishments that fabricate, package/label, test, import, distribute, or wholesale drugs with GMP requirements
3. take compliance and enforcement action when needed
4. support national consistency
5. foster transparency with industry, Canadians, international regulatory authorities and other global stakeholders

2. Scope

This policy applies to buildings where drugs are fabricated, packaged/labelled, tested, imported, distributed, or wholesaled as outlined in the following table.

Table 1.0: Licensable activities by type of establishment subject to GMP Inspection

Type of building	Fabricator	Packager Labeller	Importer	Distributor	Wholesaler	Tester
Domestic – Finished dosage forms	✔	✔	✔	✔	✔	✔
Domestic – Active pharmaceutical ingredients (APIs)	✔	✔	✔	N/A[2]	N/A[2]	✔
Foreign[1]	✔	✔	N/A[2]	N/A[2]	N/A[2]	✔

[1] Foreign buildings are not issued a DEL, they are listed on the DEL of a Canadian licence holder.
[2] Not applicable

This policy does not apply to activities that are exempt from establishment licensing – see *Guidance on Drug Establishment Licences (GUI-0002)* for more information on which activities are exempt.

The scope of this policy does not include inspections for:

- **Blood establishments** – see *Inspection Strategy for Blood Establishments (POL-0039)*
- **Semen establishments** – see *Inspection Strategy For Semen Establishments (Policy-0023)*
- **Clinical trials** – see *Compliance and enforcement approach and inspection strategy for clinical trials of drugs involving human subjects (POL-0030)*
- **Cells, Tissues and Organs** – see *Inspection Policy for Cells, Tissues and Organs Establishments (POL-0057)*

Biological drugs for veterinary use that are regulated under the *Health of Animals Act* and *Regulations* administered by Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency.

3. Introduction

Health Canada is committed to helping ensure that health products are safe for Canadians to use. We work with regulated parties to manage the health-related risks and benefits of health products by:

- minimizing health risk factors to Canadians
- maximizing the safety provided by the regulatory system
- providing clear information to help Canadians make informed decisions

To meet these commitments for drugs, Health Canada manages a GMP inspection program to enforce the Regulations and verify industry compliance.

Before drugs can be sold to Canadians, they must meet high safety and quality standards. Canadians rely on drugs produced by both domestic and foreign manufacturers, often through complex global supply chains involving both raw materials and finished dosage form. A high percentage of drugs available in Canada are imported, with many products containing ingredients from other countries.

Health Canada has developed a series of guides that outline our interpretations and how to comply with the Regulations. See *Good manufacturing practices guide for drug products (GUI-0001)* and *Good manufacturing practices guidelines for active pharmaceutical ingredients (GUI-0104)* for more information on GMP requirements.

Health Canada inspects Canadian drug establishments against GMP requirements to verify that safety and quality standards are met before drugs are sold in Canada. During a GMP drug inspection, an inspector notes deviations from the *Food and Drug Regulations* as outlined in GUI-0001 and GUI-0104, as observations in the inspection Exit Notice provided to the establishment. These observation need to be addressed by the company. For more details, see section 4 below.

Drugs can only be imported and sold in Canada if GMPs are followed where they are made. GMP standards are harmonized with other countries through international cooperation bodies such as the World Health Organization (WHO), the Pharmaceutical Inspection Cooperation/Scheme (PIC/S), and the International Council for Harmonisation (ICH).

In addition, we establish mutual recognition agreements (MRA) with regulatory authorities around the world that have equivalent GMP inspection processes and practices to Canada. The objective of an MRA is to recognize the equivalency of the drug

GMP compliance program, including inspection programs, between regulatory authorities through a formal evaluation process. Once an MRA is in place, the import of drugs from MRA countries is made easier by exchanging certificates of GMP compliance.

In order for drugs to be imported and sold in Canada, Canadian importers must demonstrate that foreign sites comply with GMP requirements and are listed on their DELs. To assess compliance, Health Canada may use inspection results from trusted international regulatory partners and performs paper-based reviews of the information to make regulatory decisions in Canada. Health Canada also performs a number of on-site inspections of these foreign buildings each year. Guidance on the type of information that should be submitted to Health Canada to assess the GMP compliance of foreign buildings can be found in the *Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080).*

Results of on-site inspections and paper-based reviews are listed in the Drug and Health Product Inspections Database (DHPID).

With Canadian establishments importing a high number of drugs manufactured abroad, Health Canada works with international regulatory partners and takes a risk-based approach to plan and conduct foreign on-site inspections. This risk-based approach helps achieve an appropriate level of regulatory oversight, efficient and effective use of resources, and a collaborative global approach for compliance and enforcement actions.

This oversight of foreign buildings helps to protect the health of Canadians and improves our contribution to the harmonization of international inspection standards, procedures, and practices. These objectives must also be balanced with expectations for Health Canada to maintain appropriate levels of oversight on the Canadian industry. This approach enables Health Canada to be adaptable to current and future realities by increasing its agility and being more present globally, while balancing oversight of domestic and foreign establishments.

Canada works hard to harmonize its GMP inspection program with international regulators. Key milestones include:

- 1997 – Division 1A (Establishment Licences) of *the Food and Drug Regulations* came into force. These regulations brought forward a licensing scheme harmonizing Canadian requirements with other international approaches. They apply to drug

fabricators, packagers/labellers, testers, distributors, importers and wholesalers.

- 1998 - MRAs are ratified with the European Community (EC) and Switzerland. Soon after, MRAs are signed with Australia and the European Economic Area – European Free Trade Association (EEA EFTA).
- 1999 – Canada is accepted as a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). A key purpose of PIC/S is to improve and harmonize technical standards and guidance documents related to GMP with a view towards global harmonization.
- 2013 – Division 1A (Establishment Licences) and Division 2 (Good Manufacturing Practices) of the *Food and Drug Regulations* are amended to include active pharmaceutical ingredients in drugs for human use.
- 2016 – Equivalency determination of Croatia completed.
- 2017 - Additional amendments to include active pharmaceutical ingredients in drugs for veterinary use. These regulations aligned Canadian requirements for active pharmaceutical ingredients with the requirements of international regulatory partners.

  The Comprehensive Economic and Trade Agreement (CETA) - Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products replaced the Canada-EU 1998 Mutual Recognition Agreement (MRA) Annex.

  Equivalency determination of Lithuania completed.
- 2018 – Recognition of APIs with Australia.

  Equivalency determination of Romania completed.
- 2019 – Re-assessment of Health Canada by PIC/s.
- 2020 – Equivalency determination of Portugal completed.
- 2021 – Canada-UK Brexit-interim arrangement and the Continuity Agreement

  Recognition of Good Manufacturing Practices extra-jurisdictional inspection outcomes.

4. Policy statement

Any establishment within the scope of this policy must comply with:

- the *Food and Drugs Act*
- the Food and Drug Regulations

Health Canada assesses GMP compliance by conducting inspections. The frequency and duration of these inspections is based on the inherent risk posed by the nature of the activities performed, and products being handled. If compliance risks are identified or other risk mitigation strategies are needed, inspections will be scheduled with increased frequency.

4.1 Inspection process

4.1.1 Before an inspection

Health Canada may, as a courtesy, give notice to an establishment before an inspection takes place. An inspector contacts the establishment to schedule the inspection. Health Canada often requests that the establishment provide certain information in advance of an inspection. An establishment applying for or holding a DEL is responsible for being in a state of readiness for an inspection at any time.

Health Canada is not required to provide advance notice of every inspection before it happens. Inspectors may not give advance notice if, for example:

- there is an immediate risk to the health and safety of consumers
- this approach supports the assessment of compliance with the Act and its regulations

Once the date of the inspection has been set and the establishment is informed, the inspection generally takes place on the date scheduled. Requests for changes to the

scheduled date will only be accommodated, at Health Canada's discretion, under exceptional circumstances and with proper justification from the establishment.

4.1.2 During an inspection

During an inspection, Health Canada inspectors observe, verify and evaluate the drug establishment's processes and review its records and procedures. Health Canada's inspections are detailed, rigorous and align with international standards.

Inspectors carefully evaluate many different areas to assess compliance with the GMP requirements in Part C, Division 2 of the Regulations, including, but not limited to:

- pharmaceutical quality system
- facility design
- integrity of data and record keeping
- qualification and validation processes
- equipment qualification and maintenance
- staff training and qualifications
- written procedures
- raw material controls
- storage facilities
- processing operations
- environmental and contamination controls
- sanitary conditions
- product testing and stability
- packaging/labelling controls and operations
- distribution and recall
- supplier qualification
- sample retentions

4.1.3 Risk observations

Inspectors make "observations" when they note areas where the establishment is not adequately meeting its regulatory requirements. Each observation is classified by level of risk:

- Critical observation (Risk 1) – describes a situation that is likely to result in a product that may result in an immediate or latent health risk, or that involves fraud, misrepresentation or falsification of processes, products or data.
- Major observation (Risk 2) – describes a situation that may result in the production of a drug not consistently meeting its marketing authorization.
- Other observation (Risk 3) – describes a situation that is neither critical nor major, but is a departure from the GMPs.

Health Canada assigns inspection ratings based on the *Risk classification guide for drug good manufacturing practices observations (GUI-0023)*.

4.1.4 At the end of an inspection

At the end of an inspection, Health Canada schedules an exit meeting to present the observations to the establishment, in the form of an inspection exit notice. This document outlines any observations (deficiencies) noted by the inspector.

Subsequent to the exit meeting, the inspector will issue the establishment a copy of the exit notice. The establishment must take prompt corrective actions to address the observations noted in the exit notice. The establishment will need to create and implement a corrective action and preventive action (CAPA) plan that includes target dates for completion.

The written response to the exit notice should include a CAPA plan. This should be developed using quality risk management principles.

Include the following in the written response that details the CAPA plan:

- details of formalized risk assessments

- outcomes of root cause analyses that clearly identify the underlying causes of the problems
- corrections, corrective actions, and preventive actions along with timelines for their implementation
- how and when to verify how well corrective actions have addressed the deficiencies

The elements outlined above will be assessed to determine acceptability of the CAPA plan.

Additional information about quality risk management and CAPA systems can be found in *ICH Q9: Quality Risk Management* and *ICH Q10: Pharmaceutical Quality Systems*, respectively.

The CAPA plan will be evaluated to determine its acceptability. If deemed deficient, the establishment will be given only one opportunity to submit an amended CAPA plan.

A deficient amended CAPA plan will inform further compliance and enforcement actions, such as:

- increased inspection frequency
- regular follow up interventions
- additional reporting requirements
- addition of Terms & Conditions to the establishment licence
- referral of product issues to the Health Product Risk Management Division

In addition, during the establishment's next inspection, if all of the identified deficiencies (observations) have not been addressed adequately, the establishment may receive a repeat observation, which may be categorized as a higher risk and may lead to a non-compliant (NC) rating.

Health Canada may also consider enforcement actions following an inspection. This can include suspending a DEL. Options are outlined in the *Compliance and enforcement policy for health products (POL-0001)*

and the *Drug good manufacturing practices (GMP) and drug establishment licencing (DEL) enforcement policy (POL-0004).*

The rated exit notice also gives the establishment an overall compliance rating. This rating is based on the nature and extent of the deviations captured by the observations recorded in the inspection exit notice. The two possible ratings are:

- Compliant (C) – the establishment has shown its activities comply with the applicable requirements of the Act and the Regulations.
- Non-compliant (NC) – the establishment has not shown its activities comply with the applicable requirements of the Act and the Regulations.

4.1.5 Reporting

Health Canada posts, on its website, summaries of drug inspections. Each inspection report card summarizes the inspection observations and the overall inspection rating, and makes them available to the public. You can find these report cards on the Drug and Health Product Inspections Database (DHPID).

GMP inspection results may be shared with international regulatory partners. Compliant GMP inspection results are used to issue DELs, as well as Certificates of GMP Compliance that are exchanged between regulators under the framework of MRAs.

4.1.6 Inspection frequency – domestic establishments

Health Canada inspects Canadian drug establishments against GMP requirements to verify that safety and quality standards are met before drugs are sold in Canada.

Inspections for new establishment licences

Health Canada inspects Canadian establishments before it issues a DEL, according to the requirements described in Division 1A of the Food and Drug Regulations.

When Health Canada receives a new application for a DEL, its service standard is 250 days to consider the application, verify GMP compliance, and determine whether or not to issue an establishment licence. An initial on-site inspection of the establishment will be performed during that period. A first regular inspection is typically conducted within 12 months of the initial inspection. This first regular inspection may be performed at an earlier or later date based on the level of risk posed by the activity being conducted, products being handled or the deficiencies found during the initial inspection.

Inspections for establishment licence amendments

When Health Canada receives an application for an amendment to a DEL, an inspection may be conducted to verify GMP compliance in support of the requested change.

New establishments applying for a DEL, and establishments making an amendment to their DEL, must be ready for an inspection when submitting their application. Health Canada requires all information and systems to be in place at the time of application.

If an establishment is not prepared for an initial inspection when contacted by an inspector, the establishment will be requested to withdraw their current application and submit a new application with all supporting information when ready for the inspection. The service standard of 250 days will apply to the resubmitted application from the time it is received by Health Canada.

If the application is not withdrawn, the initial inspection will be conducted. Lack of readiness may result in a non-compliant rating.

For more information please refer to *Management of Applications and Performance for Drug Establishment Licences (GUI-0127)*.

Regular inspections

Health Canada's inspection of domestic establishments is based on defined frequencies, similar to those of other international regulatory agencies. The inspection frequency is based on the licenced activity's level of risk. The frequency

also takes into account Health Canada's resources and priorities. Table 2.0 Domestic establishment inspection frequency provides the length of time between regular inspections.

Table 2.0 Domestic establishment inspection frequency

Activity[1]	Sterile	Non-Sterile	Inspection Frequency (years)
Sterile Fabrication (includes sterile packaging)	✔	N/A[3]	2
Non-sterile Fabrication	N/A[3]	✔	3
Primary Packaging/Labelling	N/A[3]	✔	3
Testing	✔	✔	3
Medical Mixed Gases — All Licensable Activities	N/A[3]	✔	3
Secondary Packaging/Labelling	✔	✔	4
Importation	✔	✔	4
Distribution[2]	✔	✔	4
Wholesale[2]	✔	✔	4
Medical Single Gases — All Licensable Activities	N/A[3]	✔	4

[1] If an establishment is conducting multiple activities, the highest risk activity will dictate the inspection frequency.
[2] Distribution and wholesale are not licensable activities for APIs.
[3] Not applicable

These inspection frequencies are guidelines that Health Canada may change as required. More frequent inspections, including re-inspections and re-assessments, may occur when risks have been identified based on the:

- current state of compliance and compliance history of the establishment

- size of the establishment
- types of products handled and risk of activities
- supply chain importance

Also, Health Canada may periodically perform unannounced inspections to assess and verify compliance.

4.1.7 Inspection frequency – foreign buildings

Foreign buildings must comply with Canadian GMP requirements in Part C, Division 2 of the Regulations to be listed on a Canadian DEL under Part C, Division 1A of the Regulations.

Health Canada conducts a number of foreign on-site inspections in order to enhance its regulatory oversight and global presence. Furthermore, Health Canada works in conjunction with international regulatory partners to conduct joint/concurrent inspections and collaborate closely on global drug oversight, wherever possible.

Inspections of foreign buildings may be initiated by Health Canada or requested by importers. Health Canada has adopted a comprehensive risk-based approach for selecting foreign buildings for an on-site inspection. This approach considers, among other things:

- type of GMP evidence available for the foreign building
- type and risk of activities conducted at the foreign building
- types of products handled at the foreign building
- information about the GMP compliance history of the foreign building
- availability of recent GMP evidence for the foreign building
- medical necessity of the drugs manufactured at the foreign building
- the date that new GMP evidence is required to be submitted to Health Canada

Once foreign buildings are selected, Health Canada communicates its inspection intent to the importers. Health Canada will request contractual arrangements to be signed by the importers and foreign buildings.

Health Canada is not required to provide advance notice before an inspection happens.

As per C.01A.005 of the Regulations, Health Canada also conducts reviews of inspection reports issued by qualified/regulatory authorities or in certain circumstances corporate/consultant audits. More information on this process is in Health Canada's *Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)*.

4.1.8 Inspection duration

The average time required for an inspection will vary depending on the:

- size of the establishment
- type and risk of activities
- types of products and number of products handled at the establishment
- current state of GMP compliance and compliance history

Appendix A – Glossary

Acronyms and abbreviations

API: Active pharmaceutical ingredient

C: Compliant

CAPA: Corrective Action and Preventive Action

DEL: Drug establishment licence

DHPID: Drug and health products inspections database

GMP: Good manufacturing practices

ICH: International Council for Harmonisation

MRA: Mutual recognition agreement

NC: Non-compliant

PIC/S: Pharmaceutical Inspection Cooperation/Scheme

WHO: World Health Organization

Terms

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or Food and Drug Regulations, the definition in the Act/Regulations prevails.

Corrective Action: Action to eliminate the cause of a detected non-conformity or other undesirable situation. NOTE: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (ICH Q9 and ISO 9000:2005) *(Mesure corrective)*

Exit Meeting: A meeting held subsequent to the on-site portion of the inspection, during which an unrated version of the inspection exit notice is presented to the establishment. *(Entrevue finale)*

Exit Notice: The inspection report which lists the observations or contraventions of the Food and Drugs Act and Regulations. *(Avis de fin d'inspection)*

Inspection: Assessment of compliance against any of the applicable requirements of the *Food and Drugs Act* and its associated regulations by a designated inspector. Inspections are conducted at predetermined intervals or on a risk basis. *(Inspection)*

Initial inspection: The first inspection conducted at an establishment, where not all applicable requirements of the Act and the Regulations are assessed. This is not considered to be a regular inspection. For drug sites, this is done before issuing a new/first or amended DEL. *(Inspection initiale)*

Preventive Action: Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ICH Q9 and ISO 9000:2005) *(Mesure préventive)*

Regular inspection: An inspection that is conducted against all applicable requirements of the Act and its associated regulations, and that focuses mainly on risk and the systems of control in place at an establishment. *(Inspection régulière)*

Re-inspection: A follow-up inspection carried out in response to the assignment of a non-compliant ("NC") inspection rating. The inspection is focused on, but not restricted to, those requirements of the Act and its associated regulations where contraventions were observed. *(Réinspection)*

Re-assessment: A follow-up inspection carried out in situations where the establishment was assigned an overall compliant ("C") inspection rating on the previous inspection, but the number or type of observations contained in the previous inspection exit notice require corrective action in a timely manner. The inspection is focused on, but not restricted to, those requirements of the Act and its associated regulations where contraventions were observed. *(Réévaluation)*

Appendix B – References

Legislation

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

Food and Drug Regulations
http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

Health of Animals Act
http://laws-lois.justice.gc.ca/eng/acts/H-3.3/

Quality documents

Compliance and enforcement approach and inspection strategy for clinical trials of drugs involving human subjects (POL-0030)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/inspection-strategy-clinical-trials.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

Drug good manufacturing practices (GMP) and drug establishment licencing (DEL) enforcement policy (POL-0004)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/drug-good-manufacturing-practices-establishment-licensing-enforcement-directive-0004.html

Good manufacturing practices guide for drug products (GUI-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html

Good manufacturing practices for active pharmaceutical ingredients (GUI-0104)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-

enforcement/information-health-product/drugs/guidelines-active-pharmaceutical-ingredients-0104.html

Guidance on Drug Establishment Licences (GUI-0002)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html

Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidance-evidence-demonstrate-drug-compliance-foreign-sites-0080.html

ICH Q9: Quality Risk Management
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/adoption-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use.html

ICH Q10: Pharmaceutical Quality System
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/adoption-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-guidance-pharmaceutical-quality-system.html

Inspection approach for blood establishments (POL-0039)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor/inspection-strategy-blood-establishments-0039-summary.html

Inspection Strategy for Semen Establishments (Policy-0023)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/donor-semen/inspection-strategy-semen-establishments-policy-0023.html

Management of Applications and Performance for Drug Establishment Licences (GUI-0127)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/management-applications-performance-drug-establishment-licences-0127.html

Risk classification guide for drug good manufacturing practices observations (GUI-0023)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/risk-classification-drug-gmp-observations-0023.html

Web pages

Drug and Health Product Inspections Database (DHPID)
https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections.html