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Health Products and Food Branch

Inspectorate

Medical Devices

Pre-Inspection Package

The Health Products and Food Branch Inspectorate

1-800-267-9675

www.canada.ca




Greetings

Health Canada is pleased to provide you with our new pre-inspection package to assist your organization in complying with the *Medical Devices Regulations* and preparing for an inspection by the Health Products and Food Inspectorate.

You can find all applicable laws and regulations regarding medical devices at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/legislation/acts-lois-eng.php.

As the regulator, we recognize that safety can only be achieved through the involvement of government, industry, healthcare providers and patients. The Health Products and Food Branch Inspectorate is committed to providing medical device establishments with information and guidance to meet the requirements of the *Food and Drugs Act* and the *Medical Devices Regulations*.

The following information is contained in this package:

- Fact sheet outlining the mandate and the activities of the Health Products and Food Branch Inspectorate and, specifically, as they pertain to medical devices;
- Frequently Asked Questions;
- A checklist to help your organization prepare for an inspection;
- A checklist for records that may be required in filing a problem report;
- A listing of the general elements required in a standard operating procedure; and
- An opportunity to tell us what you think about the new pre-inspection package.

In addition, we recommend that you review Health Canada's guidance and policy documents regarding medical devices found at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php.

If you have any questions related to this package or the referenced documentation, please contact us by e-mail at: MDCU_UCIM@hc-sc.gc.ca, or telephone at 1-800-267-9675, or fax at 613-963-7123.




Protecting Canadians. Sharing the responsibility.

Canada's Health Products Regulatory Enforcement Authority

The Health Products and Food Branch Inspectorate is responsible for the activities concerning compliance and enforcement of the *Food and Drugs Act* (with the exception of products regulated as foods which are the responsibility of the Canadian Food Inspection Agency), as well as the *Medical Devices Regulations*.

Inspections

An inspection program was initiated in order to improve the national compliance and enforcement program for medical devices to proactively assess the compliance of medical device manufacturers, importers and distributors. Devices imported or sold in Canada must meet fundamental safety and effectiveness requirements and must be labelled in accordance with specified labelling requirements. Manufacturers must possess evidence that their devices meet those requirements.

Quality and Safety

The primary focus of inspections is to assess compliance with sections of the *Medical Devices Regulations*, such as complaint handling, recalls, and mandatory problem reporting, as they are not assessed through other mechanisms. Companies may also be assessed for compliance with the sections of the *Food and Drugs Act* which apply to medical devices.

Shared Responsibility

Medical device safety is a shared responsibility, among industry, government and health care providers.

Frequently Asked Questions

General Information

1. Why are we being inspected?

Your company is being inspected as part of our Medical Devices Inspection Program as it currently holds a Medical Device Establishment Licence (MDEL). All companies holding a Medical Device Establishment License are subject to this program.

2. Our company is presently in possession of a CAN/CSA-ISO 13485/88 certificate under CMDCAS in addition to our MDEL. Do we still need to be inspected?

Yes. The inspection will cover the activities indicated on the MDEL.

3. Are manufacturers inspected by Health Canada?

Manufacturers of class I to IV devices that also hold MDELs are inspected by Health Canada. The inspection covers the activities related to the MDEL. Manufacturers of Class I devices that do not also hold a device licence for Class II, III or IV medical devices are also subject to the inspection program. In addition, private label manufacturers are included in the inspection program, as they are not in possession of a CAN/CSA-ISO 13485/88 certificate under CMDCAS.

4. Why are we being inspected, when another company isn't being inspected? Or, hasn't been inspected?

All companies holding a MDEL in Canada will be inspected. Every year we have a scheduled number of companies to inspect.

5. If an observation is noted and changes have to be made to our processes/activities will this be requested and applied with our competitors?

All companies holding a MDEL will be inspected and all are subject to the same requirements.

6. What is the scope of the inspection?

Compliance with the *Food and Drugs Act* and *Medical Devices Regulations* is assessed.

Generally, the following areas will be reviewed, if applicable: device labelling, device licensing, advertising, MDEL application, distribution records, handling complaint records, mandatory problem reports, recall records, procedures attested to in MDEL application, implant registration, custom made and special access devices, investigational devices, and export certificates.

Please see Appendix I in the *Guidance on the Medical Device Inspection Programme* (GUI-0064) that indicates the regulatory requirements that apply to each type of medical device activity at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm-eng.php.

7. How long will the inspection take?

For most small companies, the on-site inspection is generally completed in one day. Larger companies may require 2 to 5 days.

8. Once the inspection is completed, when will we be inspected again?

Health Canada is working towards developing an inspection cycle.

Procedures

9. What is a written procedure?

It consists of a step-by-step description that is followed by the company to carry out a process or task.

10. What is Health Canada looking for with regard to acceptable, documented procedures for handling, storage, delivery, installation, corrective action and servicing? Is there a guidance document?

Please see the *Guidance on the Medical Device Inspection Programme* (GUI-0064). Appendix II in this document outlines the interpretations in these areas which should assist in developing the applicable procedures at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm-eng.php.

11. Where can I find the company identification number (ID#) and the addresses of the manufacturers of the devices that I sell?

If you are selling Class II, III or IV devices, the name, address and the company ID# of these manufacturers may be found at **www.mdall.ca**. This web site lists all medical devices that are currently licensed for sale in Canada.

If you are selling Class I devices, there are no listings of the manufacturers of these products and no company ID# will be available. These products may come directly from the manufacturer if you are ordering directly from them, or from the product package, if ordered through another Canadian company.

Distribution Records

12. Am I required to keep distribution records?

As per section 55 of the *Medical Devices Regulations*, a manufacturer, importer or distributor of a medical device is required to retain distribution records for the longer of:

(a) the projected useful life of the device; and

(b) two years after the date the device is shipped.

Some devices may have a long useful life. If the useful life of the device is not readily available or evident, contact the manufacturer to find out what they have determined that time to be.

The Inspection

13. What can be expected during the on-site part of the inspection?

The following process can be expected during the on-site visit:

- An opening meeting to present the inspection plan and update any information;
- A tour of the facility may be conducted. This will provide the inspector the opportunity to gather objective evidence of compliance by interviewing staff, reviewing procedures and examining records;
- The devices will be inspected to ensure proper labelling [expiry dates are indicated (if needed), appropriate catalogue numbers are indicated on the package, manufacturers information is correct, bilingual labelling if required]; and
- If any non-compliant devices are found, a stop sale or recall may be requested until such time as the device receives the appropriate licensing.

Miscellaneous

14. Who can we contact if we disagree with the classification ruling of a device?

Classification rulings are handled by the Medical Device Bureau. You may contact the Bureau at 613-957-7285 and device_licensing@hc-sc.gc.ca.

15. What if we don't store any medical devices in our warehouse?

Please arrange to have a few devices available at the inspection (preferably at least one for each class and manufacturer). Alternatively, you can make copies of the device labelling. Compliance with the labelling and licensing (if applicable) requirements will be reviewed.

16. Is there a cost (financial penalty) associated with an observation?

No, there is no financial penalty.

17. Will you be asking my competitors to stop sale of their products as well?

If an unlicensed device is found during an inspection, the manufacturer of that device will be contacted and a stop sale will be requested of the manufacturer until such time as the device is licensed. The manufacturer will be required to notify all affected importers and distributors.

Trade complaints can be submitted to us. Please see the guidance document on *Health Product Complaint Form* (FRM-0317) found at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/frm-0317-eng.php. A follow-up will be conducted with the companies involved.

18. Will the outcome of the inspection be published on the Health Canada Web site?

Yes, the results of inspections will be published on-line.

19. I purchase medical devices from a company in the US, but they are shipped from a warehouse in Ontario. Should I indicate importing or distributing as my business activity?

If you would contact the company in the US in the event of problems, complaints or issues with the device, then you are acting as an importer and should identify your activities as such. Mandatory problem reporting and recall reporting to Health Canada would apply.

On the other hand, if you would report problems, complaints or issues with the device to the company in Ontario or other Canadian province, then you are acting as a distributor, and mandatory problem reporting and recall reporting to Health Canada would not apply.

20. I source large, complicated medical devices (e.g., x-ray machines) for hospitals on an as-needed basis. I have no idea who the manufacturers will be in advance of the purchase, or whether the device will be sourced domestically or will be imported. Many of my purchases will be one-time deals. How do I show my activities and list of manufacturers?

If you import at all, then it must be identified as an activity, as must distribution if you also source devices domestically. The manufacturers and classes of devices should be based on historical activity and should be carefully reviewed and updated every year in order for your renewal to be as accurate as possible.

21. How are we expected to respond to observations found during the inspection?

Your response should include a corrective action plan which addresses each observation and the preventive action taken to prevent recurrence. A time line for the completion of each observation should also be included. Corrective actions include revising current procedures, making corrections to the MDEL, labelling, etc. For most observations, you will be given time to address the observation. However, in the case of unlicensed devices found during inspections, the company will be required to stop sale of the device immediately as outlined in the *Guidance on Medical Devices Compliance and Enforcement* (GUI-0073) at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073-eng.php.

22. What is an Inspection Rating?

During an inspection, deviations or deficiencies with a specific requirement of the *Food and Drugs Act* or the *Medical Devices Regulations* are noted by the inspector, and these deviations appear as observations in the Inspection Report. A decision based on these observations is then made by the inspector and an overall rating recommendation of Compliant or Non-compliant is given at the closing meeting. A Compliant (C) rating means that the regulatory party has demonstrated that the activities are in compliance with *Food and Drugs Act* and its associated *Regulations* (companies are still responsible for any corrective action cited during a C-rated inspection). A Non-compliant (NC) rating means that the regulatory party has not demonstrated that the activities are in compliance with *Food and Drugs Act* and its associated *Regulations*. An NC rating may result when a Risk 1 observation is noted during an inspection, or when the regulatory party is not in control of its operation with numerous Risk 2 observations. Attribution of a NC rating may have serious consequences for a company, ranging from the implementation of important corrective measures, to the suspension or cancelation of the MDEL.

23. How are risk categories assigned to an observation?

The category assigned to an observation will be in relation to the nature of the risk associated with the deviation, and can vary depending on the context. Each observation will be assigned a Risk 1, 2, or 3. Additionally, an observation noted during a previous inspection (and which was not corrected) may be assigned a greater risk rating. Please see Appendix 1 in the *Guidance on Risk Classification of Medical Device Observations* (GUI-0079) for examples of Risk 1, 2, or 3 observations at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0079_ris_class-eng.php.

Medical Devices: Inspection Document Checklist*

The following documents are required for the inspection. A copy of these documents may be requested by the inspector in advance of the inspection:

- □ Copies of all the procedures that have been attested to on the MDEL application.
- □ Lists of all manufacturers of devices that are being sold by your company.
- □ Lists of all medical devices that are currently being sold by your company.
- □ A copy of the latest application that was sent to the establishment licensing office (this may be requested to ensure that the information is as current as possible).

During the on-site visit the following records will be requested for review:

- □ Distribution records of selected devices.
- □ Complaint records and associated investigation/follow-up that was conducted.
- □ Any recalls and/or mandatory problem reports that your company may have been involved with (if applicable).
- □ Records of authorizations for investigational testing on human subjects (if applicable).
- □ Records of authorizations of devices imported for special access (if applicable).

Note* It should be noted that this list is not all inclusive, and is not provided in any order of priority; additional documents may be requested prior to and/or after the inspection. In addition, some of the above documents may not be applicable in all cases.

Medical Devices: Elements Generally Found in a Standard Operating Procedure

The format for a standard operating procedure (SOP) is not mandated in regulation. However, in accordance with accepted quality system practices, a number of elements are normally included, though the titles and order may differ. These elements are summarized as follows:

Purpose	Briefly stated reason for the SOP.
Scope	Area covered (e.g., product types and sites) and any relevant exclusions.
References	List of other related procedures, standards, policies or other documents identified in or linked to the procedure, identified by title, author, date, unique traceability code, *etc*.
Definitions	Meanings of key terms used in the SOP with references to source documents, as appropriate.
Responsibilities	Functional unit(s) or individuals responsible for carrying out the procedure, or various tasks within the SOP: listed in one place and/or identified beside each task.
Instructions, Actions or Methods	Step-by-step actions that must be taken in order to achieve the stated purpose of the SOP.
Records	Specific documents generated through implementation of the SOP. Retention period, format and storage location should be included, or referenced in another SOP.
Appendices	Attachments to the SOP, each containing related information, such as, a form, checklist, flow chart or list of criteria, and specifically referenced in the SOP.
Document Control	A means of ensuring that all SOPs, forms, records, company policies, *etc*. are the most current, approved versions that reflect the manner in which activities are conducted within the company. There are many ways in which document control can be achieved: • Revision level (letter, number or combination), date of revision, effective date. • A summary table or narrative of previous revisions, dates and brief description of changes, either included or referenced in the SOP. • Distribution list identifying functions receiving the SOP. • Authorization: signatures and written dates of approval of the SOP by those individuals most responsible for its implementation.

Guidance on medical device complaint handling and recalls can be found on the Health Canada Web site at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php.

Medical Devices: Information Required for Recalls (Section 64)*

* It should be noted that this list is not all inclusive, and is not provided in any order of priority; additional documents may be requested prior to and/or after the inspection. In addition, some of the documents may not be applicable in all cases.

Device Identification

- ☐ Full name of the device(s) being recalled as found on the labelling.
- ☐ Model number of the device.
- ☐ Catalogue number(s) of the affected device(s).
- ☐ Batch, lot or serial number(s), as applicable.
- ☐ License number of the device(s), if applicable.
- ☐ Device identification number of the device(s), if known and if applicable.

Contact Information

- ☐ Full name and address of the manufacturer.
- ☐ Name, title, telephone number, fax and email of the manufacturer's representative.
- ☐ Name and address of the site of fabrication, as applicable.
- ☐ Full name and address of the importer, if applicable.
- ☐ Name, title, telephone number, fax and email of the importer's representative.
- ☐ Full name and address of the distributor(s), if applicable.

Reason for Recall, Risk Evaluation and Corrective Action

- ☐ Reason for the recall.
- ☐ Detailed description of the investigation with respect to the root cause and concerns regarding related lots or products.
- ☐ Hazard to the user/patient of using the device in its affected state, risk as determined by the recalling company (the potential for the hazard to occur).
- ☐ Date and circumstances under which the defect or potential defect was discovered.
- ☐ Determination of the recall priority (see the guidance document entitled *Guide to Recall of Medical Devices* (GUI-0054) for a discussion on this topic).
- ☐ Proposed action to prevent a recurrence of the problem, if known at this time.

Distribution Details

- ☐ Quantity of affected units by catalogue number and lot/serial number manufactured, and date range of manufacturing.
- ☐ Quantity of affected units imported into Canada by catalogue number and lot/serial number, and date range of importation.
- ☐ Name and address of all Canadian accounts/users to whom the affected devices were distributed.
- ☐ Number of affected units in stock.

Recall Strategy and Time Frames

- ☐ Recall strategy including:
  - Proposed depth, and means by which customers will be notified.
  - Copies of correspondence to customers, time frames for notification and completion of any on-site corrections, means of retrieval of affected units, instructions to customers regarding disposition.
  - Plan for confirming receipt of information by customers and follow-up with non-respondents, proposal for interim reports to the Inspectorate.
- ☐ Plan to quarantine returned product, and final disposition of affected product.
- ☐ Date of initiation of recall in Canada.
- ☐ Estimated date of completion in Canada.




Tell us what you think

The Health Products and Food Branch Inspectorate is committed to providing the health products industry with information and guidance toward achieving world class excellence in safety and quality standards.

Our new pre-inspection information package is just one way we are working to support our commitment. We are continually looking at new ways of helping you achieve international standards. To help us develop better and more effective tools in support of our shared goals, please tell us what you think.

1. I found the new pre-inspection package helpful.

   □ Strongly Agree □ Agree □ Disagree □ Strongly Disagree

2. The new pre-inspection package answered most of my questions related to the inspection process.

   □ Strongly Agree □ Agree □ Disagree □ Strongly Disagree

3. Please comment on other information or tools that you believe could help you better prepare for an inspection.

Please e-mail your feedback to:
MDCU_UCIM@hc-sc.gc.ca or fax to: 613-963-7123
www.canada.ca