



Our Mandate:

To manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across, all regions

Health Products and Food Branch Inspectorate

Guidance on Medical Device Compliance and Enforcement

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Disclaimer

This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that 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 document is to provide the medical device industry with a clear description of compliance and enforcement actions relating to the *Medical Devices Regulations (MDR)* and sections of the *Food and Drugs Act (Act)* applicable to medical devices.

2.0 Mandate

The Inspectorate is responsible for managing the national compliance and enforcement program for medical devices. This program has an establishment licensing component, a proactive inspection component and a responsive compliance verification/investigation component.

3.0 Scope

This document is applicable to any situation of noncompliance with the requirements of the *MDR* or a section of the *Act* applicable to medical devices. The main areas of the *MDR* are found in Appendix A.

This document also applies to those sections of the *Act* which apply to medical devices, including sections 3, 19, 20 and 21.

4.0 Definitions

Company: any regulated party subject to the *Food and Drugs Act* and the *Medical Devices Regulations*, including manufacturers, importers, distributors, persons, partnerships and associations.

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

Distributor: a person, other than a manufacturer, an importer or a retailer, who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

Enforcement Activities: the range of actions that may be taken to induce, encourage or compel observance of the *Act* and the *Regulations*.

Importer: a person in Canada, other than the manufacturer of a device, who causes the medical device to be brought into Canada for sale.

Manufacturer (as per the *Regulations*): means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Noncompliance: a state of nonconformity with a specific requirement of the *Act* or *Regulations*.

Recall : in respect of a medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

(a) may be hazardous to health;

(b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or

(c) may not meet the requirements of the *Act* or the *Medical Devices Regulations*.

5.0 Policy

5.1 Policy Statement

Where noncompliance with the requirements of the *Act* or the *MDR* is identified, the Inspectorate shall ensure that appropriate actions are taken by the company to address the noncompliance, based on the risk to health. If appropriate actions are not taken to comply with the requirements, the company shall be subject to enforcement action.

5.2 Guiding Principles for Compliance and Enforcement

The guidance document on compliance and enforcement for medical devices is based on the guiding principles and responsibilities outlined in the Inspectorate's *Compliance and Enforcement Policy* (POL-0001) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php), and *Recall Policy* (POL-0016) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php),

5.2.1 Transparency and Fairness

This document identifies uniform and predictable actions which are considered appropriate responses to noncompliance to the *MDR*.

Where justified by circumstances and supported by sound rationale, the Inspectorate may consider alternate actions or approaches to those specified in this document.

5.2.2 Risk Management

The degree and timeliness of actions to address noncompliances and any subsequent enforcement actions conducted by the Inspectorate are primarily based on the mitigation of risk to health.

Noncompliance with the requirements of the *Act* or the *MDR* may directly affect the safety and effectiveness of a device or group of devices. For example, the failure of a device to comply with the requirement to provide adequate directions for use can present a health risk.

Health Canada relies on the premarket review process to provide a level of assurance with respect to the safety, effectiveness, and compliance of class III and IV devices prior to permitting their sale in Canada. Noncompliance with device licensing or authorization requirements presents a potential risk to health. Failure to licence devices circumvents the premarket review required in the *MDR*. Failure to comply with post-market requirements, such as complaint investigation or recall reporting, may also pose a risk to health.

The principal mechanisms the *MDR* use to provide assurance of compliance with these requirements are device licensing for manufacturers (of class II, III and IV devices) and establishment licensing of importers, distributors and manufacturers of class I devices. Noncompliance with either device or establishment

licensing requirements creates the potential that companies may not be able to adequately identify or take appropriate corrective action regarding unsafe or ineffective devices which they have manufactured, imported or distributed.

5.3 Responsibility

According to POL-0001 (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php) where noncompliance is brought to the attention of a company by the Inspectorate or otherwise, it is the company's responsibility to take timely and appropriate action to comply. Where the action taken is considered inadequate to resolve the noncompliance, the Inspectorate may initiate enforcement actions. The enforcement actions have the primary objective of mitigating the risk associated with the noncompliance.

5.4 Response to Noncompliance

Guidance for actions to be taken to respond to noncompliance has been divided into the following five groups:

1. the requirement for device licensing (DL) or authorization (sections 26, 70 or 80),
2. the requirement for establishment licensing (EL) (section 44),
3. stop sale for class I devices (section 25),
4. device specific requirements other than licensing, authorization or stop sale, and
5. company specific requirements other than establishment licensing.

5.4.1 Noncompliance with Device Licensing or Authorization Requirements (Sections 26, 70 or 80)

This section applies to:

1. devices subject to device licensing which have never been issued a licence (other than devices subject to Parts 2 or 3 of the *MDR*),
2. licensed devices which have been subject to change requiring an amendment under sections 34 (a), (b) or (f) and have not been issued an amended licence,
3. devices which have had their licence suspended or cancelled, and
4. devices being imported or sold under the special access, custom-made, or investigational testing provisions of the *MDR* (Parts 2 or 3) which require an authorization and have not received one or have had it cancelled.

Requirement to stop noncompliant activity

When the Inspectorate has evidence that a medical device has been sold or imported without complying with the requirements of sections 26, 70 or 80 of the *MDR*, the Inspectorate issues a regulatory letter to the company having imported or sold the unlicensed or unauthorized device. The letter directs the company to

immediately stop importation/sale of the device in Canada. The company may also be asked to review other devices they manufacture, import, or sell and provide evidence of compliance with licensing and authorization requirements. The inspector can request a voluntary detention or issue a stop-sale letter onsite during an inspection, or can issue the letter by mail in the case of other compliance activities. If the company is not the manufacturer of the device, the Inspectorate will also issue a Regulatory Letter to the manufacturer of the device to stop sale of the device in Canada.

Requirement to notify customers

In the stop sale regulatory letter issued to a manufacturer, the Inspectorate will also require that the manufacturer provide written notification to anyone to whom they have sold the device.

The notification of customers must be in writing and clearly indicate the device has been imported or sold in contravention of the *MDR* and clearly direct recipients to stop any further sale or distribution of the affected devices. The notification to customers is considered to be a recall action and the company must submit section 64 and 65 information in accordance with the *MDR*.

The recall action could proceed to the end user level if justified by the risk to health. Importers and distributors receiving the notification for recall from the manufacturer should also notify their customers. Their notification to customers should direct recipients to stop sale. Importers are also required to comply with sections 64 and 65 of the *MDR*, as are manufacturers.

For licences which have been suspended, cancelled or are subject to amendment, the notification is required to be sent to anyone who has imported or has been sold the device after the cancellation or suspension date, or after the date when the amendment was required.

Requirement for confirmation of actions taken

For noncompliances identified during an inspection, confirmation of stop importation and sale is required by the closing meeting. If no confirmation is received, the Inspectorate may take enforcement action to prevent further noncompliant activity. Stop importation/sales issued during an inspection will be listed in the inspection summary section of the inspection report.

For stop importation and sale regulatory letters issued to a manufacturer, importer or distributor, a written confirmation, on the included fax-back form, is required from the company within 5 business days that they have stopped the importation or sale of the affected devices.

If written confirmation that importation or sale was stopped upon receipt of a stop importation/sale letter is not received within 5 business days, enforcement actions could be initiated in accordance with POL-0001 (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php).

Request to delay recall notification

In the following circumstances, a company may request a delay to send the recall notification to its clients, pending the issuance of the required licence, amendment or authorization. Requests for the delay of notification will be reviewed by the Regional Office responsible for the company.

1. The device in question is class II and the manufacturer can demonstrate that they currently hold device licences. If a delay is granted, the manufacturer must supply evidence that they have applied for a device licence within 5 business days after the Regulatory Letter was issued.
2. The noncompliance can be addressed through a licence amendment, which meets the criteria for a fax-back process (changes to the name of a device licence for existing device licences only, changes to the manufacturer's name or address of existing device licences, or non-significant additions or deletions). If a delay is granted, the manufacturer must supply evidence that the fax-back amendment was sent within 5 business days to the Medical Devices Bureau (MDB) after the stop sale notice was issued.
3. The device qualifies for licensing as outlined in the guidance document for private label medical devices. If a delay is granted, the manufacturer must supply evidence that they have applied for a device licence within 5 business days after the Regulatory Letter was issued.

If delays are granted in any of the above circumstances, manufacturers are required to notify the Inspectorate when they receive notification of the outcome of their licensing application. Notification will not be required if the licence or amended licence is issued. If the application is refused, the company will be required to go ahead with notification.

Other actions

For devices which are unlicensed, unauthorized, or have had their licence suspended owing to the contravention of other requirements of the Regulations, such as safety and effectiveness, the company should take additional actions to mitigate the risk in accordance with section 5.4.4. This may include a removal of the device from the market, or a public advisory.

Health Canada may also issue public notices for devices which are not in compliance with device licensing, or Part 2 or 3 authorization requirements.

5.4.2 Establishment Licensing Noncompliance

5.4.2.1 Importation and Sale in Contravention of Section 44

Where a company imports or sells a medical device without complying with the requirement in section 44 to hold an establishment licence (EL), the Inspectorate issues a regulatory letter to the company advising that these activities must cease until they apply for and receive an EL. They are required to provide a response in writing within 5 business days of the date of the Regulatory Letter.

If a satisfactory response is not received within 5 business days and/or application for an establishment licence has not been initiated, a warning letter is issued to the company reiterating the noncompliance and the actions to be taken by the company. A response is required within 5 business days. If a satisfactory response to the warning letter is not received within 5 business days, the company will be subject to appropriate enforcement action as allowed for under the *Act* and *MDR*.

5.4.2.2 Refusal to Issue an Establishment Licence

Establishment licences will be refused if there are reasonable grounds to believe that issuing such a licence would constitute a risk to the health or safety of patients, users or other persons. Failure to comply with any requirements of the *Act* or *MDR* which may impact on health and safety may be considered such grounds. The letter of refusal identifies the reason for the refusal. The applicant company may seek an opportunity to be heard but may not initiate any importation or sale subject to section 44 while waiting to be heard.

5.4.2.3 Suspension of an Establishment Licence

An establishment licence may be suspended when one or more of the following conditions are present:

1. evidence that the company has failed to comply with the requirements of the *Act* or *MDR*,
2. evidence the company made a false or misleading statement in the application, or
3. allowing the company to continue activities subject to EL would constitute a risk to the health and safety of patients, users or other persons.

Where the Inspectorate becomes aware that one or more of the above conditions exists, the company is normally given an opportunity to submit and implement a corrective action plan. This opportunity may be denied where immediate action is required to protect health and safety. If the company fails to respond or the response is inadequate, the company is subject to EL suspension.

Companies subject to EL suspension are issued a letter of intent indicating that a recommendation has been made to the Director General of the Inspectorate that the licence be suspended under section 49 or 50 of the *MDR*.

Suspension under Section 49

The letter of intent identifies the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken. If the proposed suspension is based on the outcome of an inspection or a failure to respond to corrective actions arising from the inspection, this will be referenced in the letter.

Suspension under Section 50

If a licence suspension is required to prevent injury to the health or safety of patients, users or other persons, a recommendation may be made to suspend the licence under section 50. This recommendation is submitted by a Regional Office Manager for approval by the Inspectorate Director General. If approved, a Notice of Suspension is issued without an opportunity for the company to be heard. Activities subject to EL must stop effective the date of suspension. However, the company may request, in writing, that the licence suspension be reconsidered. Within 45 days of such a request, the company is given an opportunity to be heard. The company may not resume activities subject to EL pending the outcome of the hearing. The licence may be reinstated if the situation giving rise to the suspension has been corrected or the reason for suspension was unfounded.

Companies who fail to comply with a suspension notice are subject to immediate enforcement action.

5.4.2.4 Failure to Renew an Establishment Licence and Cancelled Licences

Pursuant to section 51.1 (b) of the *MDR*, companies who fail to submit an establishment licence annual review application prior to April 1st will have their licence cancelled. The Inspectorate will send the establishment a letter stating that they are to immediately stop all licensable activities. The letter will request that the establishment confirm in writing that they have ceased licensable activities.

If confirmation is not received or there are reasonable grounds to believe activities subject to EL are still occurring, compliance verification may be conducted. If licensable activities continue, compliance and enforcement actions may be taken as described in section 5.4.2.1.

Additionally, companies who have requested to have their licence cancelled and no longer hold an EL may be subject to similar compliance and enforcement actions if they continue licensable activities.

5.4.3 Noncompliance with Stop Sale for Class I Devices

Any manufacturer not complying with directions to stop sale under sections 25 or 85 (2) (a) of the *MDR* is subject to immediate enforcement action. These companies must also determine if the situation warrants a recall of devices, using the recall procedure required under section 58 (b). The actions taken are reviewed by Health Canada to ensure they are adequate.

5.4.4 Noncompliance with Device-Specific Requirements Other than Device Licensing, Authorization or Stop Sale

Where a company does not comply with requirements of the *Act* or *MDR* which relate to a specific device or group of devices such as labelling or safety and effectiveness, the Inspectorate advises the company to take action based on the following guidelines:

1. When the noncompliance might impact the safety or effectiveness of one or more devices, the Inspectorate expects the company to:
 - a) stop importation and sale of the affected devices until such time as compliance is achieved,

- b) take immediate action to assess the risk associated with the noncompliance and develop a strategy to mitigate the risk, which may include recall activities such as advisories, corrective action, or removal from use , and
- c) take preventive action to achieve and maintain compliance.

Note: The Inspectorate may request a health hazard evaluation or risk benefit analysis from the MDB to assess risk. If the evaluation or analysis recommends specific actions to address the risk, the company is advised to take those actions.

2. When noncompliance minimally impacts the safety and effectiveness of a device, the company is asked to provide and implement a corrective action plan for resolving the noncompliance in a timely and effective manner and for preventing recurrence.

Companies who fail to conduct such actions in a timely and effective manner are subject to enforcement action which may include the following:

- a recommendation to the MDB for information requests under section 25 or 39,
- a recommendation to MDB for suspension of a device licence under section 40 or 41, or
- a recommendation to the Director General of the Inspectorate for suspension of an establishment licence, where applicable.

5.4.5 Noncompliance with Company-Specific Requirements Other than Establishment Licensing

Where a company does not comply with a requirement of the *Act* or *MDR* which relates to a procedure or action for which they are responsible for (for example, they lack a recall procedure or they fail to submit mandatory problem reports) the Inspectorate advises the company to take action according to the following guidelines:

1. Assess the risk associated with the noncompliance and determine what corrective action is required to mitigate it. The Inspectorate may request a health hazard evaluation or risk benefit analysis from the MDB to assess risk and determine if the actions proposed by the company are adequate.

For example, if a company is found to have inadequately investigated complaints, they must take immediate action to investigate any outstanding problems, assess the risks and conduct any actions required to address the risks which still remain. Similarly, companies who have failed to conduct recall actions in order to address unsafe, ineffective or noncompliant devices, must immediately take recall action for devices which could still be in distribution or use. In the case of a company failing to notify Health Canada of recalls or mandatory problem reports, the Inspectorate may request the company to supply the relevant records for a given time period, in order to assess that adequate action was taken by the company to carry out the recalls or in the case of mandatory reports, to investigate and address the problem.

2. In addition to the corrective action, the company takes appropriate preventive action to achieve and maintain compliance.

Any company not able to take required corrective action owing to a lack of records, absent or deficient procedures, or is found to be unwilling to take such actions, is subject to enforcement action focussed on addressing the risk to health. Enforcement actions may include suspension of establishment licence and recommendation to suspend device licences, where applicable.

5.5 Enforcement

In general, companies are given an opportunity to take action in response to noncompliance. However, enforcement action(s) may be taken at any time during or after an investigation or inspection, where warranted by circumstances such as lack of cooperation or an inability to address the noncompliance.

Failure of companies to respond to:

1. written notices (regulatory letters or warning letters)
2. inspection reports, or
3. letters requesting compliance actions such as recalls,

is interpreted as an indication that the company does not intend to voluntarily comply and that enforcement action is required. Companies with a history of failure to provide adequate response to noncompliance(s) may be subject to immediate enforcement action.

Note: For the purposes of this document the timeframe listed for response to a written notice from the Inspectorate is deemed to start from the date of the notice.

Enforcement actions are based on evidence of contravention of the *MDR* or section of the *Act* applicable to medical devices. They may also include contravention of sections of the *Act* during an inspection, including section 23 (3) of the *Act* which requires that inspectors shall be given reasonable assistance and be furnished with any information they may reasonably require.

The enforcement actions may include, but are not limited to, warning letters, public notifications or Safety Alerts, product seizure, recommendation for actions under sections 25 or 39, order to require and disclose information, recommendation for device licence suspension, order to modify labelling or packaging, establishment licence suspension, import refusal, mandatory recall order, injunction or prosecution.

The Inspectorate applies enforcement actions based on risk to health and considers various factors including the types and classification of the devices involved, population at risk, degree of noncompliance and the company history in responding to noncompliance.

Enforcement procedures following a noncompliance rating after an inspection are detailed in *Guidance on the Medical Device Inspection Program* (GUI-0064)(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm-eng.php).

6.0 Effective Date

June 12, 2015

7.0 Associated Documents

Compliance and Enforcement Policy (POL-0001) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)

Recall Policy (POL-0016) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)

Guidance on the Medical Device Inspection Program (GUI-0064) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm-eng.php)

Medical Devices Regulations, SOR/DORS/98-282, as amended (<http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-1.html>)

Food and Drugs Act (<http://laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html>)

8.0 Appendix A

Part 1 - General

1. Safety and Effectiveness Requirements (sections 9-20)
2. Labelling Requirements (sections 21-23)
3. Contraceptive Device Advertising (section 24)
4. Stop Sale of Class I Medical Devices (section 25)
5. Device Licensing Requirements (sections 26-43)
6. Establishment Licensing Requirements (sections 44-51)
7. Distribution Records Requirements (sections 52-56)
8. Complaint Records Requirements (section 57)
9. Complaint Handling Procedure Requirements (section 58a)
10. Recall Procedure Requirements (section 58b)

11. Mandatory Problem Reporting Requirements (sections 59-61)
12. Recall Notification Requirements (sections 63-65)
13. Implant Registration Requirements (section 66-68)

Part 2 - Custom-made and Special Access Devices

1. Authorization Requirements (section 70-74)
2. Labelling Requirements (section 75)
3. Distribution Records Requirements (section 76)
4. Incident Reporting (section 77)
5. Implant Registration Requirements (section 78)

Part 3 - Devices for Investigational Testing involving human subjects

1. Authorization Requirements (section 80, 82-85)
2. Record Requirements (section 81)
3. Labelling Requirements (section 86)
4. Advertising Requirements (section 87)
5. Distribution Records Requirements (section 88)
6. Recall Procedure Requirements (section 88)
7. Complaint Handling Requirements (section 88)
8. Mandatory Problem Reporting Requirements (section 88)
9. Recall Notification Requirements (section 88)
10. Implant Registration Requirements (section 88)

Part 4 - Export Certificates

1. Export Certificate (section 89)
2. Signature (section 90)
3. Records (section 91)
4. Retention Time (section 92)