Health Canada Santé Canada

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 Establishment Licensing and Medical Device Establishment Licence Fees

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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.

Canada

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1.0 Introduction

1.1 Purpose

This guidance document is intended to explain sections 44 to 51 of *Medical Devices Regulations (http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html)* (hereinafter referred to as the *Regulations)* of the *Food and Drugs Act (http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html)* (hereafter referred to as the *Act*) which refer to medical device establishment licensing. The Regulations outline the responsibilities of persons who import or sell medical devices in Canada, as well as the responsibilities of the Inspectorate of Health Canada. It describes what is a medical device establishment licence (MDEL) and when it is required, who is required to hold a licence, and the activities covered under an MDEL. The application process is described, including how to obtain a new licence, how and when to amend an existing licence and the annual review of MDELs. In addition, section 9 of this guidance document is intended to help MDEL applicants to understand their payment obligations under Part 3, Division 4 of *Fees in Respect of Drugs and Medical Devices Regulations (http://laws-lois.justice.gc.ca/eng/regulations/SOR-2011-79/index.html).*

This guidance document does not provide guidance on obtaining a medical device licence (MDL) that is required for manufacturers of class II, III and IV. For information related to obtaining an MDL please contact the Medical Devices Bureau (MDB) of the Therapeutics Products Directorate at:

•E-mail: device_licensing@hc-sc.gc.ca
•Telephone: (613) 957-7285
•Fax: (613) 957-6345

1.2 Background

The intent of the MDEL requirements in the *Regulations* is:

1. To ensure that the Inspectorate is made aware of:

   a) persons importing and/or distributing medical devices in Canada (including distributors located outside Canada who are selling to Canadian facilities),
   b) manufacturers of medical devices sold by the holders of MDELs (licence holder), as well as the classification of those devices,
   c) manufacturers of Class I devices who distribute their own devices.

2. To require licence holders to provide some assurance to the Inspectorate that they have met the regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint handling, recalls, mandatory problem reporting and for handling, storage, delivery, installation, and servicing, with respect to the medical devices they sell.

1.3 Scope

This document provides guidance on all aspects of MDELs mandated by Part 1 of the *Regulations*. This document also provides reference to guidance on preparing for a regulatory inspection conducted by the Inspectorate. Distributors located outside of Canada and selling in Canada are subject to the same

regulations. In addition, this document includes a section that provides guidance on how to calculate and pay fees and the fee remission process.

1.4 Definitions

• **Annual Gross Revenue**: the amount earned by an establishment during a calendar year from sales in Canada of medical devices. Sales in Canada include the exports of medical devices, except those for which section 37 of the *Food And Drugs Act* has been invoked.

• **Applicant:** for the purpose of this guidance document, an applicant is the person applying for an MDEL.

• **Ultimate Consumer:** for the purposes of this guidance document, the "ultimate consumer" is the individual who purchases or receives a medical device for their own personal use (including use within their household) or receives treatment or diagnosis with a medical device from a health care facility or provider. Businesses that purchase medical devices solely for use by their employees during work activities (e.g. first aid kits, disposable gloves) or for incidental emergency use are also considered ultimate consumers as long as they are not in the business of offering healthcare services to employees or other individuals.

• **Custom-Made Device (as set out in the *Regulations*)**: means a medical device, other than a mass-produced medical device, that

  a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;
  b) differs from medical devices generally available for sale or from a dispenser; and
  c) is:
     (i) for the sole use of a particular patient of that professional, or
     (ii) for use by that professional to meet special needs arising in the course of his or her practice.

• **Distributor**: for the purposes of this guidance document, a distributor is 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.

• **Dispenser (as set out in the *Regulations*)**: means a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient.

• **Device (as set out in the *Act*)**: means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

  a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
  b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
  c) the diagnosis of pregnancy in human beings or animals, or

d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.

- **Health Care Facility (as set out in the *Regulations*)**: means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.

- **Health Care Provider**: for the purposes of this guidance document, a health care provider is any person who provides diagnostic or therapeutic services to individuals including the provision of emergency first aid services by fire and ambulance departments.

- **Importer**: for the purposes of this guidance document, an importer is a person in Canada, other than the manufacturer of a device, who is responsible for the medical device being brought into Canada for sale.

- **Manufacturer (as set out in 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, labeling, 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.

- **Medical Device (as set out in the *Regulations*)**: means a device within the meaning of the *Act*, but does not include any device that is intended for use in relation to animals.

- **Person (as set out in the *Regulations*)**: includes a partnership and an association.

- **Retailer**: for the purposes of this guidance document, retailers are persons who sell a device, or a service utilizing a device, solely to the ultimate consumer.

  Note: Many retailers may not be aware whether devices are being purchased by ultimate consumers for their own use. However, where a sale occurs to those who are identifiable as not being the ultimate consumers, the seller is considered to be a distributor, not a retailer.

- **Sell (as set out in the *Act*)**: includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

- **Site:** for the purposes of this guidance document, a site is a building where one or more of the procedures as attested to on the application form are in place.

2.0 Legislated Requirements

Any person who imports into Canada, or sells in Canada, a medical device for human use requires an establishment licence with the exception of

- a retailer
- a healthcare facility,
- a manufacturer of Class II, III or IV medical devices who only sells:
  - medical devices for which they hold a valid licence, or
  - medical devices subject to Parts 2 and 3 of the *Regulations*,

- a manufacturer of a Class I medical device who imports or distributes solely through a licensed establishment,
- a person solely selling medical devices subject to Parts 2 and 3 of the *Regulations*
- a dispenser.

Explanatory Notes

a) Retailers are exempt from the requirement to hold an MDEL. This includes establishments who provide medical devices to ultimate consumers for their own use but are paid by a third party, such as a health insurer, as well as manufacturers of class I medical devices who sell their devices solely to ultimate consumers.

b) Manufacturers of class II, III and IV devices are exempt from the MDEL requirements for the devices the sell under their own name (ie. Those for which they hold a device licence). If they also sell medical devices from other manufacturers, they will require an MDEL for the import and/or sale of these devices.

A complete summary of exemptions to the MDEL requirements may be found in Appendix 1.

3.0 The Application Process

For the Medical Device Establishment Licence Fee, Fee Remission, and Fee Remission Requirements please see section 5. Applicants who do not follow the fee and fee remission requirements will not have their fee remission granted.

3.1 Completing an MDEL Application Form

The information required to obtain an MDEL is listed in section 45 of the *Regulations*, and includes; the name and address of the applicant, other sites, identification of a regulatory affairs contact person, the activities of the applicant, the manufacturers whose medical devices are to be sold by the applicant, and the classes of those devices. There is also a requirement for signed attestations to be made by a senior official of the applicant that documented procedures are in place in respect of distribution records, complaint handling, recalls, mandatory problem reporting and other regulatory requirements where applicable.

Medical Device Classification: It is the responsibility of the applicant to obtain information on classification of medical devices and to ascertain that the device indicated on the application has been classified as a medical device. For information on medical device classification, please refer to the Draft Guidance for the Risk-based Classification System. (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/risk5_risque5-eng.php).

It is the applicant's responsibility to determine if they require an MDEL. If it is determined that the products are not classified as medical devices, the fees associated for the examination of previously submitted MDEL applications will not be refunded.

Note: If you are importing or distributing medical devices, you application must include the information for the manufacturers from which you obtain your devices. This is the establishment that holds the device licence or class I MDEL. If you are obtaining your devices from another importer or distributor and not the manufacturer, you must still provide the manufacturer's information. You do not need to provide the distributor/importer information.

A site is a building where one or more of the procedures attested to in the application form are in place and where activities listed for the primary licence address are conducted. If there no additional sites, the primary licence address should be listed on the MDEL.

An applicant can register many sites on a single MDEL. Only list those sites where the noted procedures in the attestation are located. A sales agent, taking orders on behalf of a manufacturer where the device is sent directly to the purchaser from the manufacturer and the manufacturer is responsible for all regulatory requirements, would not be required to be hold an MDEL.

Foreign Sites – Common Error: A foreign site is not listed on a Canadian MDEL and (the same applies to a Canadian site on a licence held in a country other than Canada). A P.O. Box is not considered an acceptable licence address site.

3.1.1 Attestations and Signature Page

The attestations page of the application contains three statements with respect to documented procedures that must be in place, depending on the activities conducted by the applicant. The applicable procedures are to be identified by a check mark in the appropriate box. The Chief Executive Officer or other senior officer of the applicant's establishment must then sign the application in order to attest and to acknowledge the following:

I, the undersigned acknowledge that:

- as a senior official of the establishment named in this application, that I have direct knowledge of the procedures in place, as confirmed by the annotation above.
- selling or importing medical devices without a valid establishment licence is in contravention of section 44.(1) of the *Medical Devices Regulations* and subject to compliance and enforcement actions.
- for Class II, III, IV devices, this establishment shall only sell licenced devices, as per section 26 of the *Medical Devices Regulations*, unless authorized elsewhere in the *Medical Devices Regulations*.
- it is a serious offence to knowingly make false attestations on this application.

The attestation from a senior representative of an applicant's establishment is confirmation that procedures required under the *Regulations* are in place and confirmation that the establishment is aware of its responsibilities under the *Regulations*. It provides a level of assurance that medical devices sold or imported into Canada meet the safety and effectiveness requirements set out in the *Regulations*, and that procedures are in place to protect the public should a problem with a device be identified.

The documented procedures attested to include procedures with respect to distribution records, complaint handling and recalls, (required by paragraph 45(*g*) of the *Regulations*); mandatory problem reporting (paragraph 45(*h*) of the *Regulations*); and for handling, storage, delivery, installation, and servicing in respect of any Class II, III or IV devices, where applicable (paragraph 45(*i*) of the *Regulations*).

If the information submitted on the application is identified as being false or incomplete, the Minister may refuse to issue an MDEL. Making a false attestation regarding required procedures or listing manufacturers who do not hold valid medical device licences, are grounds for refusal to issue a licence. Please see section 7.3 for instructions on how to verify that class II, III, and IV manufacturers hold valid medical device licences.

"Documented procedures" in these sections, means procedures that are implemented and that are adequate for the purposes for which they are implemented. Guidance is provided on the Compliance and Enforcement website.(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index_e.html).

3.2 Submitting the MDEL Application

Submit the completed application form to:

ELapplicationLE@hc-sc.gc.ca

If you submit your application to Health Canada by email or fax but have other documents, such as fees, that need to be sent by mail, please include a copy of the email/fax as the cover page of the mailed information.

Fax: (613) 957-4147

Establishment Licensing, Billing and Invoicing Unit
Health Products and Food Branch Inspectorate
250 Lanark Avenue
Graham Spry Building - Second Floor
Address Locator 2002C
Ottawa, ON K1A 0K9

Please do not submit duplicate applications.

The service standard for the review of an MDEL application and the issuance of a licence is 120 calendar days, on average. This is calculated based on the date the application is received by Health Canada. In general, Health Canada will not expedite the review of an application.

For MDEL application-related information only, please contact: MDEL_questions_LEPIM@hc-sc.gc.ca

For MDEL fee related questions, please contact: ELIU_UFLE@hc-sc.gc.ca

3.3 Review of the MDEL Application

An application will be screened against the following criteria:

a) Is the information submitted complete and appropriate, relative to the licence application type, i.e. notifications, amendments or annual review applications?
b) Are the names, addresses and other sites of the applicant covered by the MDEL?

c) Are the manufacturers whose devices are sold provided in full and in the prescribed format?
d) Are all relevant fields, including attestations and signatures, completed as per the required format?
e) Is the device indicated on the application classified as a medical device and the appropriate class of device indicated?

Where an application fails to meet any one of these criteria, the establishment will be contacted to obtain the required information. Consequently, to avoid delays in the processing of your licence application, it is important to correctly complete all applicable fields in the application form. Failure to respond to information requests in a timely manner may result in the rejection of your application.

In addition, applications will be assessed for receipt of the correct payment, as per calculations based on the certified statement of revenue. Applicants will be notified if there is discrepancy in payment, and will have 30 days to pay the difference.

3.4 Decision

Under section 46(1) of the *Regulations*, if an application meets the requirements of section 45, an MDEL will be issued to the applicant. A valid MDEL is one that has been signed, dated and issued by the Delegated Authority, Health Products and Food Branch Inspectorate, for the Minister of Health. If issuance of a licence is refused due to the conditions listed in section 47 (1) and (2) of the *Regulations*, the applicant will be notified and given an opportunity to be heard.

A list of establishments with valid MDELs is posted on the Inspectorate Establishment Licences website. (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html)

4.0 Notifications and Annual Review Applications:

4.1 Notification

Under section 48 of the Regulations, licence holders are required to notify the Minister within 15 days whenever there is a change to the name or address of the licence holder or a change to the name, title or telephone number of the contact person identified on the application. The information should be sent to the Establishment Licensing, Billing and Invoicing Unit of the Inspectorate as described in Section 3.2. An amended licence will be issued that reflects the changes (if required).

4.2 Annual Review Applications

Effective April 1, 2011, an establishment licence will no longer expire on December 31 of each year, and there will be no expiry date indicated on establishment licences. As indicated in the revised *Medical Devices Regulations*, all MDEL holders must submit a request for an annual review, before April 1 of each year to continue to hold a valid licence. The applicable fees are due with the application.

As a courtesy, Health Canada will continue to send a reminder to licence holders and provide an annual review package to each MDEL holder. However, it continues to be the applicant's responsibility to ensure that an annual review application is submitted to arrive at Health Canada before April 1 of each year. When

submitting your application for annual review, please ensure all relevant changes are appropriately indicated in your application.

Failure to submit a complete annual review application before April 1 will result in the cancellation of your MDEL. Licensable activities must not continue in the absence of a valid MDEL.

Should the establishment wish to commence activities again, an application for an MDEL, along with the applicable fees, must be made. If the application is complete, a new MDEL number will be issued and licensable activities may resume.

5.0 Fees and Fee Remissions

The regulatory requirements concerning MDEL fees can be found in *Part 3, Division 4 of the Fees In Respect of Drugs and Medical Devices Regulations*. The MDEL fees set out in the regulations are to be increased annually by 2%, rounded upwards to the nearest dollar, beginning April 1, 2012.

For applications received between April 1, 2013 and March 31, 2014, the fee for the examination of an application is $7,491 for (1) an MDEL or (2) the annual review of an MDEL or (3) the reinstatement of an MDEL. Please note that notifications to MDELs (amendments) do not require payment.

Note: All dollar amounts used in this section are included only for ease of reference. Please consult the regulations for a definitive statement of fees applicable.

5.1 Time of Payment

5.1.1 General Rule

The applicable fee is payable at the time the applicant submits the application.

Applicants who have submitted insufficient payment will be charged the appropriate fee and will have up to 30 days to pay the remaining difference before interest will accrue.

Please note: For how to submit payment please follow the following instructions: "How to Pay Fees" (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/costs-couts/crpay_rcfrais_for-eng.php) that can be found on the Health Canada website.

Payment of fees by credit card or in Canadian funds is strongly advised.

5.1.2 First Year of Activities

For applicants who have not completed their first full calendar year of conducting activities under any MDEL, the payment of the applicable MDEL fee is deferred until the end of the first full calendar year.

If you have not completed your first full calendar year of activities under an MDEL, please sign the section of FRM-0292 *Medical Device Establishment Licence Application: Form and Instructions* (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/form/frm-0292-eng.php) for applicants who have not completed their first calendar year.

Any payment received for an applicant whose fee is deferred will be returned.

Health Canada will contact applicants who have completed their first calendar year of activities advising them of the requirements to pay their fee and submit a fee remission request, if applicable. Applicants will have 30 days to respond and submit the appropriate payment along with a fee remission request, if applicable.

Applicants who qualify for payment deferral may also qualify for fee remission at the time of payment (please see section 5.2.2).

Interest will be charged for all late payments. If it is determined by Health Canada that an applicant does not qualify for payment deferral, any applicable fee is immediately payable with interest. This would include applicants that have previously completed a full calendar year under an MDEL, including under another name. **Applicants will be notified, charged the appropriate fee and will have up to 30 days to pay the remaining difference before interest will accrue.**

Example:

If an applicant who has never previously held an MDEL is issued an MDEL on any day in 2013, the payment of the fee is deferred until the final business day of December 2014.

Using the same scenario above, the fee for the annual review of the MDEL that must be submitted with the application before April 1, 2014, will be deferred until the final business day of December 2014.

5.2 Remission

5.2.1General Rule

In order to support small and medium businesses, the fee for the review of an application for an MDEL can be reduced to 1% of the establishment's annual gross revenue for activities conducted under the licence. In order to obtain fee remission, a complete fee remission request must be submitted **with the application**.

If an applicant wishes to apply for fee remission, the request must be included **with the application** and must include a Certified Statement of Revenue.

A Certified Statement of Revenue is a statement signed by the individual responsible for your company's financial affairs that sets out the annual gross revenue from the sales conducted under the MDEL.

Health Canada does not provide a Certified Statement of Revenue form or template. As examples, the Certified Statement can be a signed letter on company letterhead, a signed copy of the applicant's general ledger or a signed copy of sales logs from the general ledger. The statement must clearly demonstrate the actual gross revenue from the Canadian sales of medical devices for the last

completed calendar year. For example, if the Certified Statement of Revenue is submitted to Health Canada in February 2014, it must show the revenue from sales between January 1, 2013 and December 31, 2013.

To facilitate the review process, we encourage you to submit a calculation chart with your application.

The Medical Device Establishment Licence Calculation Chart (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/calcul-chart_md-im-eng.php) is a tool Health Canada uses to help determine the total fee and the potential fee remission for an MDEL. Applicants will **only** need to enter company name, MDEL licence number, company code, and the gross revenue (box "A") for the last completed calendar year to have the total value of an MDEL licence calculated. Note: Since the calculation chart is not a signed document, it is not considered a Certified Statement of Revenue.

5.2.2 Remission for First Year of Activities

Applicants who have not completed their first year of activities will have an opportunity to apply for fee remission once their fee is due. Health Canada will contact applicants who have completed their first calendar year of activities advising them of the requirements to pay their fee and submit a fee remission request, if applicable. Applicants will have 30 days to respond and submit the appropriate payment along with a fee remission request, if applicable. At that time, applicants applying for fee remission will be required to submit the information described in section 5.2.1. Failure to submit the information in section 5.2.1 will result in the full fee being due.

5.2.3 Audited Sales Records

If, on the basis of any information available to Health Canada, the information that is supplied in support of a request for fee remission is deemed not adequate to determine the applicant's actual gross revenue, Health Canada may require the applicant to provide sales records that have been audited by a qualified independent auditor. The audited records are to be used for the purpose of determining the fee payable or the amount of the remission.

If the applicant does not submit audited sales records within 60 days after Health Canada makes an official request for such records, remission will be automatically denied. The full MDEL fee will be payable with interest.

Note that any expense incurred in having sales records audited by an independent auditor rests with the applicant.

5.3 No Credits or Refunds

The fee is associated with the examination of an application for an MDEL. Therefore, once an application has been submitted and is being processed by Health Canada, the fee is payable. If an establishment chooses to withdraw its application or cancel its licence once the application is being processed by Health Canada, the fee will not be credited or refunded.

It is the applicant's responsibility to determine if they require an MDEL. If it is determined that the products are not classified as medical devices, the fees associated for the examination of previously submitted MDEL applications will not be refunded.

Prior to submitting an application for an MDEL, it is recommended that the applicant confirm the classification of their products using the Draft Guidance for the Risk-based Classification System. (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/risk5_risque5-eng.php).To avoid the above scenario, it is the responsibility of the applicant to ensure that what they intend to import or sell is in fact a medical device.

5.4 Managing Disputes

To initiate this process, contact the Manager of the Establishment Licensing, Billing and Invoicing Unit at:

Establishment Licensing, Billing and Invoicing Unit
2nd Floor, Graham Spry Building,
250 Lanark Ave,
Address locator: 2002D
Ottawa, Ontario K1A 0K9

OR

Fax: 613-957-6711

OR

Email: ELIU_UFLE@hc-sc.gc.ca

6.0 Licence Suspension

Under Section 49 of the *Regulations*, an MDEL may be suspended if there are reasonable grounds to believe that:

a) the licence holder has contravened the *Regulations* or any provision of the *Act* relating to medical devices;
b) the licence holder has made any false or misleading statements in their MDEL application; or
c) failure to suspend the establishment licence would constitute a risk to the health and safety of patients, users or other persons.

The compliance history of the licence holder and the risk to the health and safety of patients, users or other persons of allowing the licence to remain valid will also be considered. When a decision to suspend a licence has been taken, the licence holder is given written notice of the reason(s) and the appropriate corrective action(s) to be taken. The licence holder is also given an opportunity to be heard prior to the suspension, unless immediate suspension is required to prevent injury to the health or safety of patients, users or other persons (as described in section 50 of the *Regulations*). In accordance with section 44 of the *Regulations*, as soon as an MDEL is suspended, the licence holder is required to immediately suspend all activities related to importation or sale of medical devices until the MDEL is reinstated.

Section 51 of the *Regulations* provides for reinstatement of a licence if the situation that gave rise to the suspension is corrected or the reason for the suspension was unfounded.

The "Medical Device Compliance & Enforcement Directive (GUI-0073)" (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073-eng.php) contains additional information on enforcement activities related to MDELs.

7.0 Other Regulatory Responsibilities of Licence Holders

Under the *Regulations*, an establishment licence holder has other responsibilities. This section of the guidance document describes these further obligations. It is imperative that a licence holder have access to and be familiar with the current version of the *Act* as well as the *Regulations* in order to meet the regulatory requirements.

7.1 Labelling - Section 21(1) of the *Regulations* states that no person shall import or sell a medical device unless the labelling of the device bears the information described in that section. A guidance document for the labelling of medical devices is available:

> Guidance for the Labelling of Medical Devices under Section 21 to 23 of the Medical Devices Regulations, Appendices for Labelling: Soft Contact Lenses and Menstrual Tampons (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php)

7.2. Class of Medical Devices Imported or Sold - The application for an MDEL must set out, for each manufacturer, the classes of the medical devices from that manufacturer that are being imported or sold. This requires the applicant to determine the class of the medical devices that are being imported or sold by them. The class of a particular medical device should be available from the manufacturer or may be determined by applying the classification rules listed in Schedule I of the *Regulations*. In the event of uncertainty, confirmation with the Medical Devices Bureau (MDB) in Health Canada is advised. You may contact MDB at:

•E-mail: device_licensing@hc-sc.gc.ca
•Telephone: (613) 957-7285
•Fax: (613) 957-6345

7.3 Device Licensing - Section 26 of the *Regulations* states that no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence, or an amended licence if appropriate, in respect of that device. Every establishment licence holder should put in place a mechanism to ensure that only appropriately licensed devices are imported or sold by the licence holder. All current medical device licences are listed on the MDALL website (http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp).

This information is also available from each manufacturer that an applicant lists in their MDEL application. The mechanism(s) utilized by the applicant to ensure that all medical devices that they import or sell are licensed, if required by the *Regulations*, should be appropriately referenced in a procedure as a way to verify the applicant's ability to consistently meet this requirement.

7.4 Maintenance of Records

7.4.1 Distribution Records

Section 52(1) of the *Regulations* requires that manufacturers, importers and distributors each maintain records of distribution for each device sold. The application for an MDEL contains an attestation, required by paragraph 45*(g)*, that the applicant has a documented procedure in place in respect of distribution records. Section 53 requires that the distribution records contain sufficient information to permit a complete and rapid withdrawal of the device from the market. The *Regulations* also specify minimum retention periods for distribution records (section 55) and a manner of maintaining distribution records that will allow for their timely retrieval (section 56). The time of retention for distribution records and the manner of maintenance should also be referenced in the applicant's documented procedures.

7.4.2 Complaint Handling

Section 57(1) of the *Regulations* requires manufacturers, importers and distributors to maintain records of reported problems regarding medical devices they have sold. These records must include all actions taken in response to these problems. Section 58 prescribes the requirements, to which reference is made in paragraph 45*(g)*, for documented procedures for complaint handling and recalls.

7.5 Mandatory Problem Reporting

Section 59 of the *Regulations* requires importers and manufacturers of medical devices to report certain incidents involving devices. Sections 60 and 61 specify the information that must be submitted to Health Canada in a mandatory problem report. The manufacturer of the device may permit the importer to prepare and submit the report on the manufacturer's behalf if the information to be submitted is identical (subsection 61.1(1)). This would reduce duplicate reporting. The manufacturer must inform Health Canada in writing if this is the situation (subsection 61.1(2)). A manufacturer may not prepare and submit a report on behalf of an importer.

7.6 Recalls

Section 64 of the *Regulations* requires the manufacturer and the importer of a device that is the subject of recall to submit to Health Canada the information specified in these sections on or before undertaking a recall. Section 65 requires that after completion of a recall and as soon as possible, the manufacturer and importer report to Health Canada the results of the recall and the action taken to prevent a recurrence of the problem. As referenced in subsections 65.1(1) and 65.1(2), a manufacturer may designate the importer to submit the recall information, if identical, on their behalf by notifying Health Canada in writing.

Guidance is provided in the Health Products and Food Branch Inspectorate - Recall Policy (POL-0016) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php) and Guide to Recall of Medical Devices (GUI-0054) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php).

8.0 Inspections

The Inspectorate conducts risk-based, cyclical inspections of licence holders to determine their compliance with the *Regulations*. Guidance is provided in the following documents:

Inspection Strategy for Medical Device Companies (POL-0035)
(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/pol-0035_insp_strat_doc-eng.php)

and

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)

Appendix 1: Summary of Medical Device Establishment Licence (MDEL)

The regulatory basis for MDEL exemptions is as follows:

1. Veterinary Devices

Section 1 of the *Regulations* defines "medical device" and in doing so exempts devices intended for use in relation to animals. Therefore, establishments importing or selling only veterinary devices are exempt from medical device establishment licensing under the *Regulations*.

2. Personal Use

Section 2(*b*) of the *Regulations* exempts from the application of the *Regulations* persons who import a medical device for their own personal use.

3. Dispensers

Section 4 of the *Regulations* exempts "dispensers", as defined in Section 1, from the application of many of the provisions of the *Regulations*, including the MDEL requirements. The dispenser exemption only applies to the individual dispenser. The exemption also applies to persons who perform the fitting, adaptation, or adjusting of devices as a contract service to a dispenser, e.g. an optical lab. However, persons selling the following medical devices to dispensers are subject to MDEL requirements:

a) mass produced devices which are adapted, fitted or adjusted by the dispenser for a specific patient (e.g. hearing aids, eye glasses, orthotic and prosthetic devices, contact lenses), or

b) materials which are designed for the specific purpose of being configured or arranged into a mould or shape by the dispenser or a health care professional to meet the needs of an individual (denture materials, dental alloys, orthodontic wires)

Persons who supply dispensers with materials that the dispenser uses to fabricate into a medical device, are not subject to MDEL requirements if the materials are not considered to be capable of functioning as a device without further processing or assembly, other than the molding or shaping described in exemption 3b, above (e.g. contact lens buttons or blank, hearing aid circuits).

4. Part 2 and Part 3 *Medical Devices Regulations*

Section 8 of the *Regulations* indicates that Part 1 of the *Regulations* applies only to medical devices that are not subject to Parts 2 or 3. Since Parts 2 and 3 deal with the importation or sale of custom-made medical devices, medical devices for special access and medical devices for investigational testing involving human subjects, the importation or sale of such devices are exempt from MDEL requirements. However, authorizations are required under Part 2 for importation or sale of all special access devices and for Class III and IV custom-made devices. Authorizations are also required under Part 3 for the importation or sale of Class II, III, and IV devices for investigational testing involving human subjects.

5. Regulatory Exemptions

Section 44(2) exempts the following persons from the requirement to hold an MDEL:

a) retailers;
b) health care facilities (as defined in section 1 of the *Regulations*.)
c) in the case of Class II, III or IV medical devices, the manufacturer of the medical device (for which the manufacturer holds the Medical Device Licence).
   - However, if this manufacturer also imports or sells other medical devices (that are licensed by other manufacturers), then they must obtain an MDEL with respect to the importation or sale of those other medical devices for which they are not the MDL holders..
d) in the case of a Class I device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds an MDEL.
   - However, if this manufacturer also imports or sells other medical devices, then they must obtain an MDEL with respect to the importation or sale of those medical devices.

6. Warehouses

A commercial warehouse would not require an establishment licence if they are only providing storage service and do not purchase, accept products on consignment, or enter into contracts for the sale of medical devices.

Appendix 2 – Summary of Document Changes

Document Version	Section	Change
December 12, 2012	Throughout	Editorial improvements
	2.0	Explanatory notes updated to provide better clarity
	3.0	Re-organization of this section. Updated information related to the submission of a complete application
	5.0	Previously section 9.0 Significant revisions to provide additional guidance. Updated to reflect the elimination of the fee form.
	7.6	Added reference to *Guide to Recall of Medical Devices* (GUI-0054)
April 1, 2013	Throughout	Multiple updates to fees as of April 1, 2013