

MEDICAL DEVICE ESTABLISHMENT LICENCE ANNUAL REVIEW 2013 DEADLINE TO SUBMIT YOUR ANNUAL REVIEW APPLICATION IS MARCH 31, 2013

We will accept applications for annual review received up to Sunday, March 31, 2013 at 23:59 p.m., EST. Include payment with the application. If the annual review application is not received before April 01, 2013, the establishment licence will be cancelled.

If you have ceased activities that require a Medical Device Establishment Licence (MDEL) and wish to cancel your licence, please complete the fax back form (FRM-0080) provided in the e-toolkit and return the form to us by email, fax or mail. We will send you a cancellation notice.

WHAT'S NEW THIS YEAR?

FEES: Fees increase every year by 2%. This year, the flat fee for a MDEL is \$7344.

The fee assessed is \$7344, unless your establishment is eligible for fee remission and submits a complete fee remission request, and required documents, at the time of application. If fee remission is granted, a revised invoice will be issued outlining the revised fee and any payment received.

WEBINARS: We will be offering Annual Review Webinars soon to provide additional support to applicants. If you are not already registered and wish to attend, email mdel_questions_lepim@hc-sc.gc.ca.

UPDATED FORMS & DOCUMENTS: We have updated the Application Form (FRM-0292), *Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees* (GUI-0016), the application checklist, the *MDEL Guidance Document* (GUI-0016), and the Fee Calculation Chart.

NEW TOOLS: Frequently Asked Questions

DELETED FORMS: We have eliminated the Fee Form to reduce paper and the number of forms to be submitted. The key information has been incorporated into the application form.

HOW TO SEND YOUR APPLICATION

- **Send only one application. Choose email, fax or mail.**
- Do not send duplicate applications.
- To submit hard copy information, such as fees, related to an application previously sent by email or fax, simply print the email or fax cover page that was sent and enclose with the hard copy documents. Please do not include another copy of the application.

TIPS

- Always include the establishment licence number on documents submitted.
- Always keep copies of the application and all information sent.
- Always keep the records demonstrating that the application and information has been received by Health Canada before April 01, 2013. Save the email sent or cc. yourself; Keep the facsimile transaction confirmation with number of pages and our fax number; Keep all relevant shipping or mailing records.
- Consider sending your information several weeks ahead of the deadline.

APPLICATION PROCESS

1. Review the information in your Application Form (Summary Report) and add/remove/edit any information that has changed directly on the form unless otherwise indicated.
2. Are the **contact information and addresses** accurate and up to date?
3. **Match each activity and class to the list of manufacturers** provided in the manufacturer's section. For example, if you are importing class II medical devices, at least one manufacturer of class II medical devices must be listed on the form.
4. Verify that all **sites** are correctly identified. Remove any site that is not of the same legal entity (corporation or partnership).
5. Ensure that the **manufacturer information** is still correct.
6. Complete the **attestations** on page relevant to your activities. This is a *common error!*
7. Ensure that the application is **signed and dated**.
8. Are you eligible for fee remission? **If yes, include the certified statement of revenue to the application.**
9. Include payment and submit before April 1, 2013. Keep all records.

WHERE TO SEND YOUR APPLICATION

Email: ELapplicationLE@hc-sc.gc.ca

Fax: (613) 957-6711 or (613) 957-4147

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

REMINDER — FEE REMISSIONS

Don't forget to include your Certified Statement of Revenue with your application.

FREQUENTLY ASKED QUESTIONS

WHAT PERFORMANCE STANDARDS APPLY TO MY ANNUAL REVIEW APPLICATION?

1. You will receive an acknowledgement notice by email within 2 weeks of submitting an application. Email mdel_questions_lepim@hc-sc.gc.ca if your application is not acknowledged.
2. Our time to issue a decision is on average less than 120 days from the date when the application is received by Health Canada.
3. Missing information is the number one reason that affects the time to issue a decision. We correspond by email and/or fax or telephone with the contact for the application if we have questions or require additional information.

DO I QUALIFY FOR A FEE REMISSION? (FEE REDUCTION)

You are eligible if the gross revenue generated from all activities conducted under the licence for the previous calendar year is less than \$734,400.

WHAT REVENUES DO I INCLUDE IN THE CALCULATION OF MY ESTABLISHMENT LICENCE GROSS REVENUES?

1. Revenues from medical devices sold and /or imported under the establishment licence.
2. Do not include retail sales.
3. Include revenues of medical devices sold in Canada, and exported (sold for the purpose of export).
4. Do not include medical devices sold and/or imported under a medical device licence and not the establishment licence.
5. Include revenues for the last calendar year.

HOW DO I APPLY FOR A FEE REMISSION?

With the application form, submit a request in writing that includes:

1. A signed Certified Statement of Revenue,
2. Calculation chart (optional but recommended); and
3. Payment (fees).

WHAT IS A CERTIFIED STATEMENT OF REVENUE?

A certified statement of revenue is a document signed by the authorized person responsible for the applicant's financial affairs that clearly sets out the annual gross revenue generated from Canadian sales conducted under the licence during the last completed calendar year. This can be a signed letter on company letterhead supported by sales logs, a signed copy of the applicant's general ledger, or a signed copy of the sales logs from the general ledger. There is no specific form or template provided by Health Canada.

FIND US ONLINE

Annual Review Documents – <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/ren-doc/index-eng.php>

Fees in respect of Drugs and Medical Devices – <http://www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php>

www.MDALL.ca – Your reference tool for licensed medical devices in Canada

NEED HELP?

Send fee questions to: ELIU_UFLE@hc-sc.gc.ca

Send licensing questions to: mdel_questions_lepim@hc-sc.gc.ca