Health Canada IMDRF table of contents for medical device applications guidance

On this page

Introduction and background

Purpose and scope

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of regulators committed to the acceleration of medical device regulatory harmonization and convergence. The Table of Contents (ToC) format was developed by the IMDRF to provide a globally harmonized structure and has been adopted by Health Canada for medical device regulatory activities. Health Canada is adopting the

IMDRF ToC format to encourage and support the global convergence of medical device applications. We expect that use of the ToC will reduce time and costs for both industry and the regulator, and will ultimately result in timely access to medical devices for Canadians.

This guidance incorporates content from the In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC) and Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC) published by IMDRF and regional guidance specific to Canadian submissions.

The guidance supports manufacturers and regulatory correspondents in preparing ToC-based medical device submissions to Health Canada. It outlines:

- content requirements
- system and technical specifications, including:
  - file format
  - file naming conventions
  - path length limitations
  - submission media filesystem compatibility

Detailed instructions for assembling a ToC-compliant regulatory package can be found in the Health Canada adapted assembly and technical guide for IMDRF table of contents submissions.

The ToC structure requirements apply to information packages created in support of the following:

- Pre-Market:
  - New and amendment Class II, Class III and Class IV medical device licence applications for in-vitro diagnostic devices (IVD) and non-in vitro diagnostic devices (nIVD)
  - All medical device private label licence applications
  - All fax-back (minor change) applications

    - All screening deficiency responses, clarification responses, and additional information responses associated with those submissions listed above
- Post-Market:
    - Responses to all Classes (I to IV) post-market requests (for example, responses to Section 36 or Section 39 of the *Medical Devices Regulations*)

Abbreviations and acronyms

HPFB
Health Products and Food Branch

IMDRF
International Medical Device Regulators Forum

IVD
In vitro diagnostic

nIVD
Non-in vitro diagnostic

PIS
Proprietary Information Submission

RPS
Regulated Product Submission

ToC
Table of Contents

MDD
Medical Devices Directorate

Definitions

The definitions in this section explain the scientific and regulatory terms used throughout the Table of Contents guidance documents. They are very important to review before preparing a medical device submission.

- ▶ Summary (IMDRF N9/N13)
- ▶ Full report (IMDRF N9/N13)
- ▶ In vitro diagnostic device (IVDD) (Medical Devices Regulations)
- ▶ Manufacturer (Medical Devices Regulations)
- ▶ Proprietary information submissions
- ▶ Recall (Medical Devices Regulations)

Guidance for implementation

Guidance on application content is based on the requirements set out in the IMDRF ToC as well as Health Canada-specific guidance where applicable.

The IMDRF ToC structure and content guidance documents were developed primarily for medical device submissions that require pre-market safety and effectiveness data review (such as Health Canada Class III and Class IV licence applications). Other submission transaction types (such as Class II, post-market, fax-back (minor change), private labels) typically require a more limited subset of IMDRF ToC headings.

The requirements for these various submission types are discussed in the sections below.

- ▶ Class III and IV

- ▶ Class II, private label, fax-backs (minor change)
- ▶ Responses to additional information or screening deficiency letters
- ▶ Combination products
- ▶ Post-market responses

Filing process

Transmission options

Use of the Regulatory Enrolment Process (REP)

Manufacturers are encouraged to **enroll in the Regulatory Enrolment Process (REP)** and submit their applications through the **Common Electronic Submission Gateway (CESG)** for faster and more secure processing. The CESG allows electronic submissions to be transmitted directly to Health Canada without the need for physical media or email transmission.

To submit via CESG:

- Ensure your company is **enrolled in the Regulatory Enrolment Process (REP)** and has valid Company IDs, Contact IDs, and a Dossier ID
- Prepare your submission according to the **Table of Contents (ToC) structure** and Health Canada's guidance
- Submit the regulatory transaction using the Regulatory Transaction (RT) template and, if required, the Application Information (AI) template
- Follow the CESG **file format and transmission requirements** as outlined in Health Canada's electronic submission guidance

For more information on how to register and use CESG, refer to the CESG guidance. For details about the REP process, consult the Regulatory Enrolment Process (REP) for medical devices page.

Physical media

Until REP is mandatory, submissions can be provided on physical media. Media should be sent to the appropriate address as indicated the where to submit section below.

The media formats acceptable when providing electronic ToC-based submissions are:

- Compact Disc-Recordable (CD-R) conforming to the Joliet specification
- Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format (UDF) standard
- Single and dual layer Recordable Digital Versatile Discs
- Single and dual layer Blu-ray discs
- Universal Serial Bus (USB) 2.0 or 3.0 drive
- Portable External Hard Drive with USB 2.0 or 3.0 interfaces

The media are to be labelled with the following information:

- Manufacturer’s name
- Device name
- “Protected B”
    - Note: Protected B information applies to information or assets that, if compromised, could cause serious injury to an individual, organization or government
- Virus free certification, the software used for the virus check and the date of the virus definition file(s)
- Date of application
- An identifying number for each media and total number of media provided (for example, Disc 1 of 2)

Subsequent to burning the CD/DVD or transferring data to a drive, stakeholders should ensure that all files can be opened, no files are corrupt, and that “Thumb.db” files are removed.

Important notes:

- Media should be scanned using current virus-scanning software and should be certified virus-free.
- Manufacturers should place all documents in as few CDs or DVDs as possible.
- Duplicate copies of the physical media are not required.
- Media will not be returned.

Email

Until such time as the REP process is mandatory, ToC-based submissions may be submitted to Health Canada via email provided:

- The manufacturer accepts the risk of transmitting their business information through email
- The submission does not exceed 20 megabytes
- The manufacturer has packaged the submission as a zipped file that is not password protected

Important notes:

- The submission should still follow all other guidance regarding assembly of ToC-based submission and structure of information.
- A duplicate copy should not be provided by mail.
- The body of the email should only contain the zipped submission; no other documents or related information should be included.
- Credit card information should not be included.

Where to submit

Licence applications

All medical device licensing related interactions should be directed to:

Bureau of Licensing Services
Medical Devices Directorate
11 Holland Avenue
Tower A, Second Floor,
Postal Locator: 3002A
Ottawa, ON, Canada
K1A 0K9
Telephone: 613-957-7285
Email: devicelicensing-homologationinstruments@hc-sc.gc.ca

Responses to post-market requests

Unless indicated otherwise in specific correspondence, all responses to post-market requests should be directed to:

Bureau of Investigational Testing, Special Access and Post-Market Surveillance
Medical Devices Directorate
Email: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca

Resources, tools and classification matrices

Resources

Further detailed guidance documents for medical devices are available and should be consulted when composing medical device regulatory submission. For a complete listing, please refer to Guidance documents: Medical devices.

Tools

The following additional tools are available to aid in creating applications:

- Folder templates. These are empty folder structures that use the defined abbreviated folder names:
  - nIVD Class III template [zip]
  - IVD Class III template [zip]
  - nIVD Class IV template [zip]
  - IVD Class IV template [zip]
  - Class II template [zip]
  - Private Label template [zip]
  - Fax-back (Minor Change) template [zip]
- Folder based samples. These samples are the folder structure templates above, with files added within the structure. The files include content guidance and classifications. These are for use by users who want to view the content guidance in an alternative format and can be used similar to the folder templates above, to build submissions. **Important:** Do not include any of the sample files in your submission.
  - nIVD Class III sample [zip]
  - IVD Class III sample [zip]
  - nIVD Class IV sample [zip]
  - IVD Class IV sample [zip]
  - Class II sample [zip]
  - Private Label sample [zip]
  - Fax-back (Minor Change) sample [zip]

Classification matrices

Classification matrices are detailed tabular listings of heading classification created for various submission types. These are intended to provide users with a bird's eye view of the sections that are required for

each submission type and are also intended for users who have their own submission building software to configure:

- Class III/Class IV nIVD Classification Matrix [Excel - 48 kb]
- Class III/Class IV IVD Classification Matrix [Excel - 58 kb]
- Class II/Fax-back (Minor Change) Classification Matrix [Excel - 45 kb]

Complete definitions and discussion of heading classifications is provided in the Health Canada adapted assembly and technical guide. We strongly recommend applicants familiarize themselves with the headings.

Access to information

Information provided to Health Canada by manufacturers is subject to the provisions of the *Access to Information Act*. Trade secrets or confidential scientific, technical, commercial, or financial information is protected from disclosure by this Act. According to policy, information regarding medical device regulatory activities that have been received or are being processed is also considered confidential. Once a licence has been issued, basic information about a device, such as that listed in section 32(1) of the Medical Devices Regulations, is considered public information.

Note about guidance documents in general

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments, which means they do not have the force of law. This means that it may be possible to comply with the regulations in ways other than those set out in the guidance. Health Canada suggests that regulated parties discuss alternatives with the relevant program in advance.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents. It is the regulated party's responsibility to ensure that they meet all applicable legal requirements, including those in the Food and Drugs Act and the regulations.

Contact information

Any questions or concerns related to this guidance document or its use should be directed to:

Bureau of Licensing Services
Medical Devices Directorate
11 Holland Avenue
Tower A, Second Floor,
Postal Locator: 3002A
Ottawa, ON, Canada
K1A 0K9
Telephone: 613-957-7285
Email: meddevices-instrumentsmed@hc-sc.gc.ca
The email subject line should be: “IMDRF ToC Question(s)”

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