Health Canada IMDRF table of contents for medical device applications guidance

Health Canada Santé Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Lignes directrices de Santé Canada pour les demandes d'homologation d'instruments médicaux fondées sur la table des matières de l'IMDRF

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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)

A summary should include a brief synopsis of the:

(1) purpose
(2) methods
(3) acceptance criteria
(4) results
(5) discussion and conclusions

Outliers and deviations should be reported with the results. Results should be stated quantitatively with appropriate statistical context where applicable (for example, value ± SD, confidence intervals, etc.).

The summary should specifically address:

1. Why the characteristic being evaluated is of interest
2. Why the particular methods are being used to evaluate the characteristic, if applicable including why a regional or harmonized/recognized standard/guidance has or has not been complied with
3. How the stated acceptance and sample size are scientifically supported
4. What device was tested and how it relates to the devices that will be marketed
5. Why the tested components are representative of the range of devices that will be marketed
6. Whether the summary has been previously submitted and reviewed by the regulator, including identification of the device and the reference number for the submission

7. The extent to which the duties and functions of a study (for example, testing, monitoring, etc.) have been conducted by an external organization (for example, contract research organisation or individual contractor)

Full report (IMDRF N9/N13)

Typically includes a complete, detailed description of the objective of the assessment, the methods and procedures including when applicable why a regional or harmonized/recognized standard/guidance has or has not been complied with, study endpoint(s), pre-defined pass/fail criteria, deviations, results, discussion and conclusions, and may include data. Complete, detailed support of method selection, worst case justification, study endpoint selection, and pass/fail criteria should be included.

In vitro diagnostic device (IVDD) (Medical Devices Regulations)

An *in vitro* diagnostic device is a medical device that is intended to be used in vitro for the examination of specimens taken from the body.

Manufacturer (Medical Devices Regulations)

A Manufacturer is 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.

Proprietary information submissions

Proprietary Information Submissions are used when firms that manufacture or process the device under contract to the manufacturer elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Medical Devices Directorate (MDD) in the form of a Proprietary Information Submission. The manufacturer or device sponsor should inform these firms of the need to provide detailed information on the device. Manufacturers referencing information held in a Proprietary Information Submission submitted by another company must obtain permission from the owner of the file each time the file is accessed. The letter of permission should indicate the extent of information to be considered for each application.

Recall (Medical Devices Regulations)

A recall is:

(a) A recall ordered by the minister under section 21.3 of the Food and Drugs Act, or
(b) Any action taken by the manufacturer, importer or distributor of a medical device, after the device has been sold, 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

i) may present a risk of injury to health
ii) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety, or
iii) may not meet the requirements of the Food and Drugs Act or the *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 III and IV applications require a comprehensive pre-market review. Submissions follow the ToC folder structure and reflect both IMDRF requirements and Health Canada-specific expectations. For detailed content guidance and conditions refer to the following:

- Class III nIVD applications content and classification guidance
- Class IV nIVD applications content and classification guidance
- Class III IVD applications content and classification guidance
- Class IV IVD applications content and classification guidance

Class II, private label, fax-backs (minor change)

Class II, private label, and fax-back (minor change) applications have significantly different evidentiary requirements from Class III and IV applications. While the ToC is used for these, only select folders are required and content guidance is specific to this context. For detailed content guidance and conditions refer to the following:

- Class II application content and classification guidance
- Private label application content and classification guidance
- Fax-back (minor change) application content and classification guidance

Responses to additional information or screening deficiency letters

Responses to requests from Health Canada must clearly identify the application number of the associated application. Responses to screening deficiency letters, clarification requests, and additional information letters must be provided in a question and answer format and be accompanied by a copy of the original Health Canada letter. This information is to be filed within Section "1.01-Cover Letter" and the substantial supporting information must be structured using the same format as the initial application.

Note: Your additional information response should not contain information that was previously submitted within the same application. Only submit documents that have been modified and place them in the appropriate folders with a clear reference to the changes outlined in the cover letter.

Combination products

A combination product is a therapeutic product that combines a drug component and a device component (which by themselves would be classified as a drug or a device), such that the distinctive nature of the drug component and device component is integrated in a singular product.

For further information on combination products and how they are classified please refer to the policy on drug/medical device combination products.

Combination products classified as devices are regulated under the *Medical Devices Regulations* and applications can be created following the IMDRF ToC format.

For further guidance please contact the Medical Devices Directorate at devicelicensing-homologationinstruments@hc-sc.gc.ca.

Post-market responses

The evidentiary requirements for post-market interactions differ significantly from licence applications. For more detailed guidance for post-market ToC submissions, refer to the post-market submission guidance.

Note: Responses to Section 36 and Section 39 letters should follow the format of an AI/deficiency response as discussed in the responses to additional information or screening deficiency letters section above.

How-to and system requirements

Specific guidelines for building an application in the IMDRF ToC format, including system requirements, are detailed in the Health Canada adapted assembly and technical guide for IMDRF table of contents submissions. It is essential that readers are familiar with this guidance before building an application in this format.

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 in 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]
- Class III/Class IV IVD Classification Matrix [Excel]
- Class II/Fax-back (Minor Change) Classification Matrix [Excel]

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)”