# Table of contents post-market submission 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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## Table of Contents



# Heading classifications and content examples

Not all folders (headings) are required for every submission. While the Table of Contents (ToC) is used for these interactions, only select folders are required for post-market submissions, and content guidance is specific to this context. A sample folder structure is shown below:

- Licence name
  - 1-REGADMIN
    - 1.01-CoverLetter
    - 1.03-ListofTerms-Acronyms
    - 1.05-ListofDevices
    - 1.10-Pre-SubmissionCorrespondence-PreviousRegulatorInteractions
  - 2-CONTEXT
    - 2.04-DeviceDescription
      - 2.04.03-HistoryofDevelopment
    - 2.06-GlobalMarketingHistory
      - 2.06.01-GlobalMarketHistory
      - 2.06.02-IncidentReports-Recalls
      - 2.06.03-SalesIncident-RecallRates
    - 2.11-OtherSubmissionContextInfo
  - 4-CLINICAL
    - 4.05-RWD
    - 4.06-Post-MarketSurveillanceData
  - 5-LABELLING
    - 5.02-Product-PackageLabels
    - 5.03-PackageInsert-InstructionsforUse
    - 5.04-e-labelling
    - 5.05-HealthcareProfessionalLabelling
    - 5.06-PatientLabelling
    - 5.07-Technical-OperatiorManual

- 5.08-PatientFileStickers-Cards-ImplantRegistrationCards
- 5.09-ProductBrochures
- 5.10-OtherLabelling-PromotionalMaterial

The table below outlines the classification, applicable conditions and examples of content for each heading.

**Legend**

- R = Required
- CR = Conditionally required
- O = Optional
- NR = Not required

## All classes (I to IV) for IVD and non-IVD post-market requests and additional information responses to post-market requests

| Chapter 1: Regional administrative | | | |
|---|---|---|---|
| **Folder name** | **Classification** | **Condition** | **Examples** |
| 1.01-Cover Letter | R | N/A | Cover letter or email response from manufacturer. |
| 1.03-List of Terms/Acronyms | O | N/A | List of terms or acronyms used in the transaction. |
| 1.05-Listing of Device(s) | CR | Required for Class I<br>Include when applicable or requested for Class II, III, IV | List of devices including trade or product names, catalogue or reference numbers. |
| 1.10-Pre-Submission Correspondence and Previous Regulator Interactions | R | N/A | Post-market request letter or email. |

| Chapter 2: Submission context | | | |
|---|---|---|---|
| **Folder name** | **Classification** | **Condition** | **Examples** |
| 2.04-Device description | CR | If applicable to request | |
| 2.04.03-History of Development | CR | If applicable to request | Description of design changes and rationale for changes when requested/implemented. |
| 2.06-Global Market History | CR | If applicable to request | |
| 2.06.01-Global Market History | CR | If applicable to request | Countries where device is licensed and date of licensing. |
| 2.06.02-Incident Reports and Recalls | CR | If applicable to request | Global and Canadian complaints, incident reports and summaries, root cause analysis, investigation update / report, corrective actions, recall information. |
| 2.06.03-Sales, Incident and Recall Rates | CR | If applicable to request | Global and Canadian incident rate (including rates in relation to sales), sales data. |
| 2.11-Other Submission Context Information | CR | When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other | • Health Canada requested information (post market) incident issue analysis (trending analysis).<br>• A summary of individual safety and effectiveness analyses, summary reports required under specific regulatory provisions, or evaluation documents that are not |

| | | | |
|---|---|---|---|
| | | headings of this chapter. | otherwise captured under designated headings.<br><br>• Post-market device safety issue-related analysis and benefit and/or risk analysis documents.<br><br>• Listing or description of previous risk mitigation measures implemented or planned to address the post-market issue.<br><br>For more information see Guidance on summary reports and issue-related analyses for medical devices |

| Chapter 4: Clinical evidence | | | |
|---|---|---|---|
| **Folder name** | **Classification** | **Condition** | **Examples** |
| 4.05-Real World Data | CR | If applicable to request | Device registry, medical records data |
| 4.06-Post-Market Surveillance Data | CR | If applicable to request | |

| Chapter 5: Labelling and promotional material | | | |
|---|---|---|---|
| **Folder name** | **Classification** | **Condition** | **Examples** |
| 5.02-Product/Package Labels | CR | If applicable to request | Device package label |
| 5.03-Package Insert/Instructions for Use | CR | If applicable to request | Current instructions for use, package insert, directions for use. |
| 5.04-e-labelling | CR | If applicable to request | |
| 5.05-Healthcare Professional Labelling | CR | If applicable to request | Physician labelling, Physician educational material. |
| 5.06-Patient Labelling | CR | If applicable to request | Patient brochure, patient consent form, patient educational material. |
| 5.07-Technical/Operators Manual | CR | If applicable to request | Maintenance manual. |
| 5.08-Patient File Stickers/Cards and Implant Registration Cards | CR | If applicable to request | |
| 5.09-Product Brochures | CR | If applicable to request | |
| 5.10-Other Labelling and Promotional Material | CR | If applicable to request | Any other documents that come with the device. |

## Tools

The following additional tool is available to aid in creating post-market submissions:

- Folder templates

## Submission filing process

For filing process and transmission options, refer to the Health Canada IMDRF table of contents for medical device applications guidance page.