Class IV IVD applications content and classification 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.

Également disponible en français sous le titre :
Lignes directrices sur le contenu et la classification des demandes d'homologation d’instruments diagnostique in vitro de classe IV

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Table of Contents

IMDRF common content and IMDRF Health Canada content may contain minor formatting or editorial edits compared to the source material. These changes were made to conform with the Government of Canada's guidelines for web content.

Chapter 1: Regional administrative

Folder name: 1-REGADMIN

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

1.01 Cover letter

Folder name: 1.01-CoverLetter

IMDRF common content

a) The cover letter should state applicant or sponsor name and/or their authorized representative/s, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals
b) If applicable and accepted by the regulator, it should include information pertaining to any master files referenced by the submission

c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample)
d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated
e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s)
f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided
g) Identification of the regulatory jurisdiction(s) in which marketing is sought

Note: The cover letter should not contain any detailed scientific information.

Health Canada guidance

Any information submitted to Health Canada should be accompanied by a cover letter. The cover letter should include the purpose of the application and a brief description of the package being submitted. It may also include proprietary information pertaining to the submission. The Table of Contents (ToC) structure requirements also apply to information packages created in support of all Screening Deficiency Responses, Clarification Responses, and Additional Information Responses. Summaries and full reports, when applicable, should be provided in a ToC-compliant package.

Classification

New and amendment applications: Required

1.03 Terms and acronyms

Folder name: 1.03-ListofTerms-Acronyms

IMDRF common content

Terms or acronyms used in the submission that require definition, should be defined here.

Classification

New and amendment applications: Required

1.04 Application form, administrative information

Folder name: 1.04-ApplicationForm-AdministrativeInfo

IMDRF Health Canada content

Health Canada application forms should be included here.

Health Canada guidance

Obtain the appropriate Class II, III, or IV medical device licence application form. For more information on how to complete the application form for a medical device licence, consult:

- Guidance on how to complete the application for a new medical device licence

For applications submitted through the Regulatory Enrolment Process (REP), the Class II, III, or IV medical device licence application forms are not required. Instead, applicants must complete the Regulatory Transaction (RT) template and, if applicable, the Application Information (AI) template, which generate the required REP Extensible Markup Language (XML) files. These XML files replace the standard application forms and must be included in the regulatory transaction. Do not submit the standard application forms, as the information is already captured within the XML files. For more information, consult:

- Regulatory enrolment process (REP)

Classification

New and amendment applications: Required

1.05 Listing of devices

Folder name: 1.05-ListingofDevice(s)

IMDRF common content

A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each:

a) the identifier (for example bar code, catalogue, model or part number, UDI)
b) a statement of its name/description (for example Trade name, size, intended use)

Notes:

i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant.

ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit.

Health Canada guidance

The listing of devices is part of the medical device licence application form. A separate file in this folder is not required for submissions sent on physical media or by email until REP becomes mandatory. Once REP becomes mandatory, all Medical Device Licence (MDL) submissions must be submitted electronically via the Common Electronic Submission Gateway (CESG). At that time, submissions via physical media or email will no longer be accepted.

For applications that are submitted through the REP, applicants should complete the Device Details spreadsheet found in the REP for medical devices page.

Please ensure that there are no additional security settings applied to submitted files. This includes password protection, restricted access, Digital Rights Management (DRM), or Information Rights Management (IRM). Files with these settings may be blocked by Health Canada's security policies, preventing these documents from being accessed.

Classification

New applications: Conditionally required – If application is submitted through REP

Amendment applications: Conditionally required – If application impacts the manufacturer's device identifier listing and is submitted through REP

1.06 Quality management system, full quality system, other regulatory certificates

Folder name: 1.06-QMSFullQSorOtherRegulatoryCerts

IMDRF Health Canada content

Health Canada will only accept MDSAP certificates that have been issued by recognized auditing organizations.

Classification

New licence applications: Required

Amendment licence applications: Not required

1.09 User fees

Folder name: 1.09-UserFees

IMDRF Health Canada content

Health Canada user fee forms should be included here.

Health Canada guidance

When submitting an application for a medical device licence, please refer to the Medical device application fee form for detailed instructions. They must be carefully followed to avoid delays in the processing of your application. Guidance on fees for the review of medical device licence applications can be found in the Guidance Document: Fees for the Review of Medical Device Licence Applications.

Classification

New and amendment applications: Required

1.10 Pre-submission correspondence, previous regulator interactions

Folder name: 1.10-Pre-SubmissionCorrespondence-PreviousRegulatorInteractions

IMDRF common content

a) During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the regulator and the applicant. Further, the specific subject device may have been subject to previous regulatory submissions to the regulator. The contents should be limited to the subject device as similar devices are

addressed in other areas of the submission. If applicable, the following elements should be provided:

i. List prior submissions or pre-submissions where regulator feedback was provided
ii. For previous regulatory submission, include identification of applicable submission reference number
iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application
iv. Issues identified by the regulator in prior submissions (that is, clinical study applications, withdrawn/deleted/denied regulatory submission) for the subject device
v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor
vi. Explain how and where the prior advice was addressed within the submission

Or

b) Affirmatively state there has been no prior submissions and/or pre-submission interactions for the specific device that is the subject of the current submission

Note: The scope of this section is limited to the particular regulator to which the submission is being submitted (for example Health Canada does not need pre-submission information relating to interactions with ANVISA).

Classification

New and amendment licence applications: Conditionally required – When relevant to the application

1.13 Letters of reference

Folder name: 1.13-LettersofReference

IMDRF common content

Where applicable, letter from the owner of any separate document referenced in the submission (for example Master File or previous regulatory submission), granting access to the information in the referenced document. The letter should include the information of the applicant who cited the separate document (for example Master File or previous regulatory submission), the product name, the document number that has been filed, and the page number/chapter information of the separate document authorized to be cited.

Classification

New and amendment applications: Conditionally required: When a master file is referenced

1.15 Other regional administrative information

Folder name: 1.15-OtherRegionalAdministrativeInfo

IMDRF common content

Heading for other administrative information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Note: To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong elsewhere in this chapter

Chapter 2: Submission context

Folder name: 2-CONTEXT

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

2.02 General summary of submission

Folder name: 2.02-GeneralSummaryofSubmission

IMDRF common content

a) Statement of the device type (for example Tacrolimus test system, blood specimen collection device, calibrator) and name (for example trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (that is, studies that are unique to the risks of this device type).
b) Summary of submission, including:
    i. the type of submission (for example new, amendment, change of existing application, renewal)
    ii. if amendment/supplement, the reason of the amendment/supplement
    iii. if a change to existing approval, description of the change requested (for example changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers)
    iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission)

IMDRF Health Canada content

If amendment or new submission based on currently licenced device(s), the Canadian medical device licence number(s) should be provided along with the description of the change requested.

If amendment, there may be multiple sections where there is “no change”. These folders would thus be considered “Not applicable”. A list of these sections may be provided here, identified as “no change” and then the appropriate folders would be excluded from the submission.

If amendment or new submission, if a report can fit into multiple sections, only one copy should be included and references to the single copy provided in other sections where the information might be applicable.

If requesting priority review per Section 15 of the application form, the justification should be provided here.

Health Canada guidance

For amendment submissions, the general summary should clearly identify which sections of the application are impacted by the proposed changes.

A brief risk-based justification should be included to explain why these specific sections are affected and why other sections remain unchanged.

Classification

New and amendment applications: Required

2.04 Device description

Folder name: 2.04-DeviceDescription

IMDRF common content

No content at this level.

Classification

New and amendment applications: Required

2.04.01 Comprehensive device description and principle of operation

Folder name: 2.04.01-ComprehensiveDeviceDesc-PrincipleofOp

IMDRF common content

a) A general description of the device, including:
   i. The device name
   ii. What does it do?
   iii. Who uses it and for what? (high level statement)
   iv. Where to use it? (places/environment where the device is intended to be used)
   v. General description of the principle of the assay method or instrument principles of operation
   vi. Description of the components (for example reagents, assay controls, calibrators, cassette, etc.) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers, probes, etc.)

vii. If applicable, labelled pictorial representation (diagrams, photos, drawings)
viii. If system, how the components relate?
ix. If applicable, identify if the device incorporates software/firmware and its role
x. If applicable, identify the instrument(s) required to perform the test

b) Product specification, including:
   i. Physical characteristics of relevance to the end user (dimensions, weight)
   ii. If applicable, technical features and operating modes
   iii. If applicable, operating specifications and performance characteristics (for example electrical power requirements, settings and associated allowable ranges/limits, units of measure, temperature and humidity limits, throughput (number of tests per hour), analytical and clinical sensitivity and specificity)
   iv. If applicable, a complete list of the configurations/models of the devices and a summary of the differences in specifications (comparison table and/or pictures/diagrams with supporting text)
c) Describe the different specimen types that can be used for this device (for example serum, plasma, urine, cerebrospinal fluid), including any additives that are required (for example anticoagulant).
d) Describe the use of controls. If applicable, a list of compatible control materials or control material specifications.
e) Description of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device.
f) If approved by the regulator, provide the approval number and identification for each of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device.
g) If applicable, indication of biological material or derivate used in the medical device, including:
   a. origin (human, animal, recombinant or fermentation products or any other biological material)
   b. source (for example blood, bone, heart, any other tissue or cells)

    c. where a significant risk is identified, a brief summary of evaluations performed to minimize biological risks, in particular, with regard to viruses and other transmissible agents

h) Description of the collection and/or transport container(s) provided with the IVD medical device or a description of specifications or recommended collection and/or transport container(s).
i) If applicable, a listing of assays that are compatible with the instrument.
j) If applicable, a listing of compatible instruments.
k) A list of any software to be used with the IVD medical device and a description of its role in the delivery of the intended purpose.
l) If applicable, engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission).

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device.

IMDRF Health Canada content

If the application is an amendment, this section should describe the up-to-date device as applied for in the amendment, that is**,** including the modifications. Modifications (for example changes in design, performance and indications) should be further detailed in Section 2.04.04 below. Components or accessories that can be sold separately should be identified.

Health Canada guidance

With respect to (g), a list of biological materials is not normally required. Usually for an IVDD, risk associated with biological materials is mitigated in the labelling (for example warnings and precautions) as well as by using control material that has been shown to be free of potentially infectious material (i.e. either tested and shown to be negative or else subject to an acceptable inactivation procedure).

Classification

New and amendment applications: Required

2.04.02 Material specifications

Folder name: 2.04.02-MaterialSpecifications

IMDRF common content

Details of relevant material identifications and specifications, including critical raw materials and components should be provided. Information should include complete chemical and physical characterization of all component materials.

Note: If applicable, chemicals should be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – When relevant to the amendment

2.04.03 Description of device packaging

Folder name: 2.04.03-DescriptionofDevicePackaging

IMDRF common content

a) A brief description of the packaging of the devices, including the packaging configuration and materials involved. This is not intended to include shipping/transport packaging.
b) Specific packaging of accessories marketed together with the IVD medical devices shall also be described.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – **Required** if there have been changes in the packaging since the previous submission or if the packaging is relevant to the submission (for example, there has been a change in shelf life or sterilization methods)

2.04.04 History of development

Folder name: 2.04.04-HistoryofDevelopment

IMDRF common content

For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version).

For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and performance of the final IVD medical device design.

IMDRF Health Canada content

It is highly recommended that a description of all changes made to the device since the issuance of the last medical device licence or licence amendment be provided for a device that has had a previous version licensed in Canada.

Health Canada Guidance

For devices that currently hold a licence in Canada, include any changes (significant, manufacturing, or non-significant) that have occurred since the device was licensed or last amended and not just those limited to the subject of this application.

Classification

New licence applications: Required

Amendment licence applications: Required

2.04.05 Reference and comparison to similar and/or previous generations of the device

Folder name: 2.04.05-Ref-ComparisontoSimilarand-orPreviousGen

IMDRF common content

a) A list of the similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject regulator
b) Description of why they were selected
c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device

IMDRF Health Canada content

a) If the application is an amendment to a licenced device or is based on a modification of a licensed device, a description of the modifications is required (for example changes in design, performance, and indications).
b) Comparisons can be used to support the safety and effectiveness of the device if they are made to a currently licensed device in Canada. If this method is used, ensure the Canadian Medical Device Licence Number of the comparator is stated. Include a comparison of indications for use and the technology between the comparison device and the subject device. The comparison device does not need to be manufactured by the same manufacturer.

Health Canada guidance

If the licence or licence amendment involves an instrument that is part of a series, for example, Analyzer ABC, Analyzer ABC-light, Analyzer ABC-semi-automated, etc., a summary and a brief history of the instrument series should be provided. This is applicable for all situations, even if an instrument is licensed on a separate licence, if the previous model is discontinued, etc. Sufficient information should be provided to enable Health Canada to understand the relationship between the instrument and the other instruments in the series. The information should list the instruments in the series, indicating the variation(s) in names (if applicable), the catalog numbers, and the licence numbers. The differences and similarities between the instruments should be highlighted and/or provided in a table format.

This information should be provided with every application and amendment related to the instrument and also with every assay that is intended to be used with the instrument(s), if

applicable. A tabular, flowchart, or schematic representation of the information is recommended.

When adding a device identifier, comparative information is necessary to validate compliance with licence type requirements. Include a comparison table that outlines all differences between the devices represented by the new identifiers and a closely related licensed comparator(s).

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If applicable to the amendment.

2.05 Indications for use and/or intended use

Folder name: 2.05-Indications-IntendedUse-Contraindications

IMDRF common content

No content at this level

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

Classification

New and amendment applications: Required

2.05.01 Intended use, intended purpose, intended user, indications for use

Folder name: 2.05.01-IntendedUseandIndications

IMDRF common content

This section should include, **as appropriate:**

a) **Intended use:** The statement of intended use should specify what specific disorder, condition, or risk factor of interest (that is, the analyte to be measured) is detected and the purpose provided by the device (for example screening, monitoring, diagnosis or aid to diagnosis). It should identify:

   i. instruments on which the device can be used
   ii. if the assay is automated or not
   iii. is the IVD medical device qualitative or quantitative
   iv. and the specimen types (for example serum, plasma, urine, cerebrospinal fluid), including any additives that are required (for example anticoagulant)
b) **Intended user:** Lay person or professional?
c) Identify if the device is intended for **single or multiple use**
d) **Indications for use:**
   i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use
   ii. If applicable, information about patient selection criteria
   iii. If applicable, when/where the use of the IVD medical device should be avoided
   iv. If applicable, information about intended patient population (for example adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended
e) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated, and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval

Notes:

i. The statements of intended use and indications for use must be **as presented in the labelling**.
ii. If more than one device is included, the information should be provided for each device.

IMDRF Health Canada content

The content of this section should be contained in a single body of text.

Health Canada guidance

The Guidance Document - Labelling of In Vitro Diagnostic Devices should be consulted for additional guidance.

Classification

New and amendment applications: Required

2.05.02 Intended environment, setting for use

Folder name: 2.05.02-IntendedEnvironment-Setting

IMDRF common content

a) The setting where the device is intended to be used (for example home use, domestic use, self-testing, near-patient, point of care). Multiple options can be indicated
b) If applicable, environmental conditions that can affect the device's safety and/or performance (for example temperature, humidity, power, pressure, movement

Health Canada guidance

The Medical Devices Regulations defines near-patient testing device as an in vitro diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside. This definition includes both point of care and self-testing. If a device is described as a near-patient testing device, it should be clarified if it is intended to be used for self-testing or home-use purposes or not.

Classification

New and amendment applications: Required

2.06 Global market history

Folder name: 2.06-GlobalMarketHistory

IMDRF common content

No content at this level

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

Classification

New and amendment applications: Required

2.06.01 Global market history

Folder name: 2.06.01-GlobalMarketHistory

IMDRF common content

a) Up to date indication of the markets (all countries or jurisdictions) where the device is already marketed, including any marketing under compassionate use regulations
b) Should include history of the marketing of the device by any other entity in as much detail as possible, acknowledging that detailed information may not be available in all cases
c) Include a list of all countries in which the device has been removed from marketing for any reason related to the safety or effectiveness of the device

IMDRF Health Canada content

a) If the subject device is different in any way (for example design, labelling, specifications, indications) from those approved or marketed in other jurisdiction, the differences should be described.
b) The month and year of market approval in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made.
c) For each of the markets listed in (a) above, a statement of the commercial names used in those markets **or** a clear statement that the commercial names are the same in all jurisdictions
d) State the date of data capture for the market history data
e) If the subject device has been the subject of any previous compassionate use and/or clinical trials this should be identified and, if applicable, relevant reference numbers provided

If there is any approval number, given to the device by the regulator authority of the markets (country or jurisdictions) where the device is already marketed, this identification must be informed.

a) If applicable, market history should include data for previous generations of the device.
b) Information regarding any Canadian Investigational Testing Authorizations should be included.

In this context, compassionate use includes **any** Special Access Authorizations.

Health Canada guidance

If the device has not previously been licensed in Canada, this should be stated. The authorization reference numbers from the regulatory agencies (for example United States Food and Drug Administration (FDA) 510k or PMA number) should be included.

Classification

New and amendment applications: Required

2.06.02 Incident reports and recalls

Folder name: 2.06.02-IncidentReports-Recalls

IMDRF common content

a) List adverse events/incidents associated with the device and a statement of the period associated with this data
b) If the number of events is voluminous, provide a summary by event type that states the number of reported events for each event type
c) List of the IVD medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case
d) A description of any analysis and/or corrective actions undertaken in response to items listed above
e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there

have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device

Note: It is acknowledged that the definition of recall may vary from one jurisdiction to another.

Health Canada guidance

All incident reports and recalls in Canada including international market involving previous version(s) of the device, Special Access request(s), and Investigational Testing Authorization request(s) should also be summarized here.

Classification

New and amendment applications: Required

2.06.03 Sales, incident and recall rates

Folder name: 2.06.03-SalesIncident-RecallRates

IMDRF common content

a) A summary of the number of units sold in each country/region and a statement of the period associated with this data.
b) Provide the rates calculated as follows for each country/region:
    i. Incident rate = # adverse events/incidents divided by # units sold expressed as a percentage
    ii. Recall rate = # recalls divided by # units sold expressed as a percentage

    Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported.
c) Critical analyses of the rates calculated (for example, Why are they acceptable? How do they break down in terms of incidents? Is there some outlier data that has driven the rates up? Are there any trends associated with any sub-groups of the devices that are subject of the submission (for example, size, version)?).

Notes:

i. It is acknowledged that the definition of recall may vary from one jurisdiction to another.
ii. Sales in this context should be reported as the number of units sold.

Health Canada guidance

For devices that have a long marketing history (more than 10 years), a summary of the number of units sold in each country/region (sales) for the most recent five years can be provided in lieu of a complete marketing data.

Classification

New and amendment applications: Required

2.07 Post-market study plans

Folder name: 2.07-Post-MarketStudyPlans

IMDRF common content

Post-market study plans may include clinical or nonclinical study plans. The documentation provided here will not include final reports and analysis, and instead includes study plan information only. This may include:

a) Study objectives
b) Study design
c) Subjects and sites information
d) Endpoints (primary and secondary)
e) Summary of data analysis plan
f) Length and frequency of follow-up

Note: Post-market non-clinical or clinical data from one region provided during the pre-market phase to a second region would be considered non-clinical or clinical data for the second region and would reside in Chapter 3 or Chapter 4, respectively.

Classification

New and amendment applications: Optional

2.08 Risk management

Folder name: 2.08-RiskManagement

IMDRF common content

a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an **acceptable** level. Plans can be considered part of the risk management documentation
b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits
c) Where a standard is followed, identify the standard

Health Canada guidance

The risk assessment should be conducted on the version of the device(s) under review. If the application is an amendment or a modification of a previously licensed Class IV device, the risk assessment should focus on the new and/or modified risks and their mitigation. If the original risk assessment is updated, the new risks or modified risks should be clearly highlighted. It is recommended that the current version of ISO 14971-1, entitled Medical devices **–** Application of risk management to medical devices, be consulted.

Classification

New and amendment applications: Required

2.10 Standards

Folder name: 2.10-Standards

IMDRF common content

No content at this level.

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

Classification

New and amendment applications: Conditionally required – If any sub-headings are required

2.10.01 List of standards and guidance documents

Folder name: 2.10.01-ListofStandards

IMDRF common content

This section should include:

a) If applicable, a list of the standards that have been complied with in full or in part in the design and/or manufacture of the device
    i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance
    ii. If partial compliance, a list of the sections of the standard that:
        - are not applicable to the device, and/or
        - have been adapted, and/or
        - were deviated from for other reasons – discussion to accompany

b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified

c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified.

Health Canada guidance

The use of standards is not compulsory. The manufacturer may choose to demonstrate safety and effectiveness independent of any international or national standard.

Demonstrating conformity with Health Canada-recognized standards facilitates the premarket review process. Conformity with other more general standards, e.g., device-specific standards that may not encompass all aspects of device performance, can also streamline the premarket review process.

Health Canada's guidance on using standards to support compliance with the Medical Devices Regulations may be consulted for assistance.

Classification

New licence applications: Conditionally required – If demonstrating that device complies with standards

Amendment licence applications: Conditionally required – If there are standards that have been applied in relation to the amendment

2.10.02 Declaration and/or certification of conformity

Folder name: 2.10.02-Declarationand-orCertificationofConformity

IMDRF Health Canada content

The applicant is advised to prepare the Declaration of Conformity form to recognized standards using Health Canada's Declaration of Conformity form. Refer to the guidance on using standards to support compliance with the Medical Devices Regulations and the current list of recognized standards for medical devices.

Health Canada guidance

If the standard is recognized by Health Canada and if the acceptance criteria specified in the standard can be met with pass or fail results, then in some cases it may not be necessary to review the test data for those aspects of the device addressed by the standard. For example, a Declaration of Conformity to a Health Canada recognized electrical or electromagnetic compatibility standard will usually eliminate the need to provide the test data. In most cases, however, a summary of the test data is required even though a Declaration of Conformity is provided, particularly when acceptance criteria are not specified in the standard. For example, if conformance is declared to CLSI EP5, Evaluation of precision of quantitative measurement procedures; approved guideline, acceptance criteria and a summary of the precision study results are required.

Classification

New licence applications: Conditionally required – If demonstrating that device complies with standards

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment

2.11 Other submission context information

Folder name: 2.11-OtherSubmissionContextInformation

IMDRF common content

Heading for other submission context information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Note: To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.

Classification

New and amendment applications: Conditionally required – When information does not belong in any of the other headings of this chapter

Chapter 3: Analytical performance and other evidence

Folder name: 3-ANALYTICALPERF

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

3.05 Analytical performance

Folder name: 3.05-AnalyticalPerf

IMDRF common content

No content at this level.

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

Health Canada guidance

Manufacturers must justify their chosen study design for the appropriate sub-chapter. This can be achieved by clearly indicating the use of standards in premarket submissions and appropriately identifying any referenced standards in their Premarket Review Submission. If the study design deviates from Health-Canada recognized standards, clear justifications should be provided.

Manufacturers opting for alternative study designs should include a rationale supporting the validity of their approach.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If any sub-headings are required

3.05.01 Stability of specimen(s)

Folder name: 3.05.01-StabilityofSpecimens

IMDRF common content

Information regarding and studies to support the stability, storage and where appropriate, transport, of all of the specimen type(s) identified in the labelling, including any and all recommended additives (for example anticoagulants) is to be provided in this section. This should include:

a) For each specimen type identified in the labelling, a description of the recommended storage parameters and when applicable, transport conditions (for example duration, temperatures and freeze/thaw cycles)
b) A justification on the selection of the studies performed
c) Provide summary of the evidence that falls within this category
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

e) A discussion of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject device.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.01.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

For example, the structure will look something like this

Level 3: Storage of serum samples for 7 days at 2-8ºC or 4 days at -20ºC.
    Level 4: Summary
    Level 4: Full Report
Level 3: Validation of 3 freeze/thaw cycles for serum samples
    Level 4: Summary
    Level 4: Full Report.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report

        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.01.01.01 Summary

Folder name: 3.05.01.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.01.01.02 Full report

Folder name: 3.05.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive full report is **required** for each study/test presented in this section.

3.05.02 Validation of specimen

Folder name: 3.05.02-ValofSamples

IMDRF common content

Studies to support the validity of specimen type(s) used in the analytical and clinical studies as representative of all of the sample type(s) identified in the labelling, including any and all recommended additives (for example anticoagulants), as well as contrived specimens used in certain analytical studies are to be included in this section. This should include:

a) A list of the specimen type(s) used, including any additives (for example anticoagulants), in each of the analytical performance studies. If the same specimens are used for all analytical studies this can be stated and the specimen type identified
b) For any or all of the analytical and clinical studies, if a particular specimen type(s) including additives (for example anticoagulants), has been chosen as representative of other specimen types identified in the labelling, this should be described and supported
c) If the preparation of the specimen has not followed the protocol described in the current labelling, this should be identified and validated
d) A justification of the selection of the studies performed
e) Provide summary of the evidence that falls within this category
f) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

g) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.02.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created for each study under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.02.01.01 Summary

Folder name: 3.05.02.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.02.01.02 Full report

Folder name: 3.05.02.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive full report is **required** for each study/test presented in this section.

3.05.03 Metrological traceability of calibrator and control material values

Folder name: 3.05.03-MetrologicalTraceability

IMDRF common content

Evidence that supports the metrological traceability of values assigned to calibrators and trueness control materials. This should include:

a) A description of all calibrators and trueness control materials associated with the system
b) A justification of the selection of the studies performed
c) A summary of the evidence that falls within this category, including for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

e) A statement of why this category of study is not applicable to this case

Notes:

i. Precision control materials used during analytical studies to establish the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method.
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.03.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (that is, Summary first followed by the Full Report second).

Further, as described in the *Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions* for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.05.03.01.01 Summary

Folder name: 3.05.03.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.05.03.01.02 Full report

Folder name: 3.05.03.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.05.04 Accuracy of measurement

Folder name: 3.05.04-Accuracy

IMDRF common content

No content at this level.

Note: The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness. While measurement trueness, affected by systematic error, is normally expressed in terms of bias, measurement precision, affected by random error, is naturally expressed in terms of standard deviation. Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required -If any sub-headings are required.

3.05.04.01 Trueness

Folder name: 3.05.04.01-Trueness

IMDRF common content

This section should provide a summary of information and evidence relating to the trueness of the measurement procedure. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. This should include:

a) A rationale for the reference standard or method(s) used
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.04.01.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.04.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.04.01.01.01 Summary

Folder name: 3.05.04.01.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada Guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.04.01.01.02 Full report

Folder name: 3.05.04.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive full report is **required** for each study/test presented in this section.

3.05.04.02 Precision (Repeatability and Reproducibility)

Folder name: 3.05.04.02-Precision

IMDRF common content

A summary of evidence that supports the precision characteristics of the measurement of the subject IVD medical device is to be included in this section. This should include:

a) A justification of the selection of the studies performed.
b) A summary of the evidence that falls within this category, including:
    i. Repeatability estimates and a brief summary about the studies used to estimate, as appropriate, within-run variability

ii. Reproducibility estimates and a brief summary of the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators (intended users) and instruments. Such variability is also known as **“Intermediate Precision”**

c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Notes:

i. Studies should include the use of specimens that represent the full range of expected analyte (measured) concentrations that can be measured by the product, as claimed by the manufacturer.

ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device.

Health Canada guidance

If a device is fully automated, site-to-site and operator-to-operator variability may not be relevant for reproducibility studies; justification should be provided.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.04.02.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.04.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – This is **required** for each study/test presented in this section.

3.05.04.02.01.01 Summary

Folder name: 3.05.04.02.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.04.02.01.02 Full report

Folder name: 3.05.04.02.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section.

3.05.05 Analytical sensitivity

Folder name: 3.05.05-AnalyticalSensitivity

IMDRF common content

Evidence that supports the analytical sensitivity of the subject IVD medical device is to be included in this section. This may include studies to establish the limit of blank (LoB), limit of detection (LoD), and/or limit of quantitation (LoQ). This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

Details regarding the study design should include, but are not limited to, the following.

The number of replicates tested at each concentration should be provided as well as a description of the method and calculation used to determine assay sensitivity. When applicable, the studies should include well-characterized, confirmed positive samples. Where applicable, samples representative of the different clades or strains of the pathogen detected should be used.

Ninety-five percent confidence intervals (CI) should also be provided.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.05.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.05.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – This is **required** for each study/test presented in this section.

3.05.05.01.01 Summary

Folder name: 3.05.05.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.05.01.02 Full report

Folder name: 3.05.05.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section.

3.05.06 Analytic specificity

Folder name: 3.05.06-AnalyticSpecificity

IMDRF common content

Evidence that supports the analytical specificity (interference, including as appropriate, selectivity, and cross reactivity) of the subject IVD medical device is to be included in this section. This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category

c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

Typically, studies supporting analytical specificity involve adding the potential interferent to the positive and negative samples and determining any difference relative to the control sample to which no interferent or cross-reacting substance/agent has been added. Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

- substances used for patient treatment (for example therapeutic drugs, anticoagulants, etc.)
- substances ingested by the patient (for example over the counter medications, alcohol, vitamins, biotin, foods, mouthwash, personal care products, etc.)
- substances added during sample preparation (for example preservatives, stabilizers)
- substances encountered in specific specimen types (for example haemoglobin, lipids, bilirubin, proteins)
- analytes of similar structure (for example precursors, metabolites) or medical conditions unrelated to the test condition, including specimens negative for the assay but positive for a condition that may mimic the test condition (for example for a hepatitis A assay, test specimens negative for hepatitis A virus, but positive for hepatitis B virus)

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.06.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.06.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.06.01.01 Summary

Folder name: 3.05.06.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada Guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.06.01.02 Full report

Folder name: 3.05.06.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.05.07 High dose hook effect

Folder name: 3.05.07-HighDoseHookEffect

IMDRF common content

Evidence that supports the absence of a high dose hook effect or prozone effect. This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

High dose hook effect should be determined for each claimed analyte. In the description of the study design, specify the method used to determine the analyte concentration and include a rationale for the highest dose evaluated.

Classification

New licence applications: Conditionally required – When any testing/study is conducted in support of the submission under the parent heading subject, this is required for each study/test.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.07.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.07.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.07.01.01 Summary

Folder name: 3.05.07.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.05.07.01.02 Full report

Folder name: 3.05.07.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.05.08 Measuring range of the assay

Folder name: 3.05.08-MeasuringRange

IMDRF common content

Evidence that supports the measuring range (linear and non-linear measuring systems). This measuring range should include the lower limit of quantification. This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

Details regarding the study design should include, but are not limited to, the following.

Details regarding the study design should include a description of the analyte (measurand) levels and how the levels were established, as well as a description of the specimen type and matrix and how the samples were prepared for use in the study. The number of samples and the number of replicates at each concentration should be provided. Ninety-five percent confidence intervals (CI) should be provided.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.08.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.08.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.08.01.01 Summary

Folder name: 3.05.08.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.05.08.01.02 Full report

Folder name: 3.05.08.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is required for each study/test presented in this section

3.05.09 Validation of assay cut-off

Folder name: 3.05.09-ValofAssayCut-off

IMDRF common content

Evidence that supports the determining assay cut-off is to be included here. This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:

a) the population(s) studied (demographics/selection/inclusion and exclusion criteria/number of individuals included)
b) method or mode of characterization of specimens
c) statistical methods for example, Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required -Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.09.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.09.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required: **Required** for each study or test presented in this section

3.05.09.01.01 Summary

Folder name: 3.05.09.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.05.09.01.02 Full report

Folder name: 3.05.09.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.05.10 Validation of the assay procedure

Folder name: 3.05.10-ValoftheAssayProcedure

IMDRF common content

This section should provide a summary of information and evidence supporting the validity of the assay procedure in terms of important reaction conditions (for example reaction time, reaction temperature, reagent volume, reading time). This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device

Health Canada guidance

Classification

New licence applications: required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05.10.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.10.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created for each study under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.10.01.01 Summary

Folder name: 3.05.10.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.05.10.01.02 Full report

Folder name: 3.05.10.01.02-Report

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06 Other studies

Folder name: 3.06-Other

IMDRF common content

No content at this level.

Classification

New and amendment applications: Conditionally required – When information does not belong in any of the other headings of this Chapter

3.06.01 Electrical systems: safety, mechanical and environmental protection, and electromagnetic compatibility

Folder name: 3.06.01-ElectricalSystems

IMDRF common content

Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include:

a) A justification of the selection of the studies performed
b) A summary of the evidence that falls within this category
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device

Health Canada guidance

Electrical safety, mechanical and environmental protection, and electromagnetic compatibility may be demonstrated by compliance to an international or national standard. Where a recognized standard exists, a Declaration of Conformity to the recognized standard may be provided. IEC 61010-1 and -2 standards are frequently used for electrical safety and IEC 61326-1 and -2 for electromagnetic compatibility.

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required, and the justification should be provided.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.01.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly

and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
  - 1-Summ
    - TR1525Summ.pdf
  - 2-Report
    - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
  - 1-Summ
    - TR4584Summ.pdf
  - 2-Report
    - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.01.01.01 Summary

Folder name: 3.06.01.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.01.01.02 Full report

Folder name: 3.06.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.02 Software/firmware/programmed or programmable medical

Folder name: 3.06.02-Software-Firmware

IMDRF common content

No content at this level. This section and associated sub-sections should include studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished IVD medical device. It should also address all the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation should be organized according to software or hardware systems.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission.

3.06.02.01 Software/firmware description

Folder name: 3.06.02.01-Description

IMDRF common content

The software description should include:

a) A comprehensive overview of significant software features and functions, which may include images, flow charts, and state diagrams as needed to adequately explain the software functionality
b) The version of the software. The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided
c) Identification of the IVD medical device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of off-the-shelf software (if applicable), a description of the realization process

If the product is a machine learning-enabled medical device (such as adaptive models, natural language processing, neural networks, and related approaches), please provide, as applicable:

i. a detailed description of each algorithm/model, including its inputs, outputs, data selection and management for training, testing, and validation (terminology may differ in different regions)
ii. model selection and evaluation
iii. risk management activities
iv. materials/approaches used to provide transparency;
v. post-market performance monitoring activities

Health Canada guidance

All performance studies should be conducted with the software version as used in the finished device. Otherwise, rationale demonstrating that the software version tested does not impact the outcomes of the validation studies must be provided. The software version used in validation studies should be clearly identified.

If the software or a previous version of the software has been reviewed by Health Canada, this should be clearly stated and appropriate references provided (for example application and/or licence number).

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.02 Risk management file (including hazard analysis)

Folder name: 3.06.02.02-HazardAnalysis

IMDRF common content

The risk management file should be provided and include the risk management plan, risk assessment (for example hazard analysis), and risk management report.

The risk assessment (for example hazard analysis) should take into account all device hazards associated with the IVD medical device's intended use.

For Software that is part of a system, a risk assessment should be performed on the system comprising the software and its whole hardware environment and noted in the software documentation with reference to the particular section of the premarket submission.

IMDRF Health Canada content

The risk management file in this section should specifically relate to the software/hardware. Overall risk analysis should be placed in section 2.08.

For the risk control measures in the risk assessment or hazard analysis, there should be verification of the implementation of the risk control measures and verification of the effectiveness of the implemented risk control measures (that is, the implemented risk control measure reduces risk). This can be accomplished by tracing the identified hazard to the verified specific risk control measures (for example a requirement ID in the SRS and SDS, a test name and identifier in the testing documentation that shows pass/fail results, a user manual name and identifier, a training manual name and identifier).

Classification

New licence applications: Conditionally required – When software is part of the device

Amendment licence applications: Conditionally required – When relevant to the amendment

3.06.02.03 Software requirement specification (SRS)

Folder name: 3.06.02.03-SRS

IMDRF common content

The Software Requirements Specifications (SRS) documentation should describe the needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (for example risk management file, software design specification, system and software architecture design chart, software testing).

The SRS documents the requirements for the software which typically specifies inputs and outputs, functions that the software will perform, hardware, performance, interfaces, user interaction, error definition and handling, intended operating environment, safety and security related requirements derived from a risk assessment (hazard analysis) and all ranges, limits, defaults, and specific values that the software will accept.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.04 System and software architecture design (SAD) chart

Folder name: 3.06.02.04-SADChart

IMDRF common content

The System and Software Architecture Design (SAD) Chart should consist of detailed diagrams of the modules, layers, and interfaces that comprise the device, their relationships, the data inputs/outputs and flow of data, and how users or external products (including information technology (IT) infrastructure and peripherals) interact with the system and software. If the System and Software Architecture Design Chart is included in

another document, such as the SRS, a reference to the location of the System and Software Architecture Design Chart in the submission should be included.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.05 Software design specification (SDS)

Folder name: 3.06.02.05-SDS

IMDRF common content

Software Design Specification (SDS) documentation should be provided, including sufficient information to understand the technical design details of how the software functions, how the software design completely and correctly implements all the requirements of the SRS, and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.

In terms of the relationship between the SRS and the SDS, the SRS describes what the software function will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the device software function was clear and unambiguous, with minimal ad hoc design decisions.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.06 Traceability analysis

Folder name: 3.06.02.06-TraceabilityAnalysis

IMDRF common content

A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.

IMDRF Health Canada content

The Traceability Analysis can be incorporated into the SRS documentation.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.07 Software life cycle process description / software development, configuration management, and maintenance practices

Folder name: 3.06.02.07-SoftwLifeCycleProcessDesc

IMDRF common content

The Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices description should describe the software development life cycle and the processes that are in place to manage the various life cycle activities.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.08 Software testing as part of verification and validation

Folder name: 3.06.02.08-SoftwareV-V

IMDRF common content

Provide an overall description of the verification and validation activities performed for the final software version. You should provide the applicable test protocols and reports including the expected results, observed results and pass/fail determination.

Note: Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

Health Canada guidance

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1–2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the amendment. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

3.06.02.08.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.02.08.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.02.08.01.01 Summary

Folder name: 3.06.02.08.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.02.08.01.02 Full report

Folder name: 3.06.02.08.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.02.09 Software version / revision level history

Folder name: 3.06.02.09-RevisionLevelHistory

IMDRF common content

The software version / revision level history documentation should include the history of software versions that were tested and documented as part of verification and validation activities. This typically takes the form of a line-item tabulation including the date, version number that was tested and a brief description of all changes in the version relative to the previously tested version.

The last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version.

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.10 Unresolved software anomalies

Folder name: 3.06.02.10-UnresolvedAnomalies

IMDRF common content

Documentation should include a list of unresolved anomalies present in the software with the following items (for example in tabular format) for each unresolved anomaly:

i) A description of what the anomaly is and what root cause(s) of the anomaly could be

ii) Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly

iii) Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations;

iv) Outcome of the evaluation; and

v) Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s)

Classification

New licence applications: Conditionally required – When software is part of the device.

Amendment licence applications: Conditionally required – When relevant to the amendment

3.06.02.11 Cybersecurity

Folder name: 3.06.02.11-Cybersecurity

IMDRF common content

For a description of the Cybersecurity Common Content, please refer to IMDRF/CYBER WG/N60 FINAL:2020 "Principles and Practices for Medical Device Cybersecurity"

IMDRF Health Canada content

Please consult the Pre-market requirements for medical device cybersecurity.

Health Canada guidance

Cybersecurity considerations should be included when a medical device contains or consists of software. If cybersecurity considerations are not addressed, provide evidence to support this decision.

This should include, but is not limited to, the following:

- Cybersecurity vulnerabilities and risk analysis
- Cybersecurity control measures
- Traceability matrix linking cybersecurity controls to identified vulnerabilities and risks

This documentation ensures that all relevant cybersecurity risks have been properly assessed and managed throughout the development lifecycle.

Classification

New licence applications: Conditionally required – When the results of a risk assessment suggest that there are safety and effectiveness concerns relating to cybersecurity of the device, this is required.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.02.12 Interoperability

Folder name: 3.06.02.12-Interoperability

IMDRF common content

If the IVD medical device can communicate with other devices. Evidence to support the interoperability should be provided.

Classification

New licence applications: Conditionally required – When the results of a risk assessment suggest that there are safety and effectiveness concerns relating to the interoperability of the device, this is required.

Amendment licence applications: Conditionally required – When relevant to the amendment.

3.06.03 Cleaning and disinfection validation

Folder name: 3.06.03-Clean-DisinfectVal

IMDRF common content

Contains information on the validation of cleaning and disinfection instructions for reusable devices, including evidence to support maintenance of performance when subject to this

procedure over a number of cycles that is representative of the IVD medical device's expected useful life. Information to be included in this section includes:

a) If applicable, a discussion of how the number of cycles that is representative of the IVD medical device's expected useful life has been determined
b) A justification of the selection of the studies performed
c) A summary of the evidence that falls within this category
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

e) A statement of why this category of laboratory study is not applicable to this case

Notes:

i. This applies most typically to devices intended for Point of care and/or home use (near patient testing) involving whole blood.
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

Health Canada guidance

Demonstration of disinfection effectiveness can be made through viral challenge of material used to fabricate the device or by using a disinfection product with a Canadian Drug Identification Number (DIN) that has included evidence of inactivation of HBV in the Canadian DIN product monograph. In the latter case, the disinfection instructions provided in the device labelling must align with those in the product monograph.

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required -Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.03.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.03.01.01 Summary

Folder name: 3.06.03.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.03.01.02 Full report

Folder name: 3.06.03.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.04 Usability/human factors

Folder name: 3.06.04–Usability-HumanFactors

IMDRF common content

Studies specifically assessing the instructions and/or IVD medical device design in terms of impact of human behavior, abilities, limitations, and other characteristics on the ability of the IVD medical device to perform as intended should be included here. This should include:

a) State the test environment and relation to the intended use environment
b) A justification of the selection of the studies performed
c) A summary of the evidence that falls within this category
d) A discussion and conclusion to support why the evidence presented is sufficient to support the application

Or

e) A statement of why this category of laboratory study is not applicable to this case

Notes:

i. If a clinical study has been conducted that includes usability/human factors endpoints, **reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.**
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

Health Canada guidance

Near patient IVDDs include Point-of-Care (POC) and Home-Use (self-testing) devices. Applications involving near patient IVDDs require a consumer field evaluation, which is a summary of studies conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use. These studies evaluate the performance of the device when used by the intended users without assistance, following instructions provided in the labelling.

The studies should also include a summary of results obtained from a questionnaire completed by the representative subjects following their use of the device. The

questionnaire should evaluate the robustness and ease of use of the device, including an assessment of legibility and clarity of the Instructions for Use or Package Insert. For devices intended to be used for near-patient testing, a results interpretation study may be required, evaluating the ability of intended users to interpret all possible results using mock devices.

Classification

New licence applications: Conditionally required – If any sub-headings are required.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.04.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.04.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:

    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.04.01.01 Summary

Folder name: 3.06.04.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.04.01.02 Full report

Folder name: 3.06.04.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.05 Stability of the IVD

Folder name: 3.06.05–Stability

IMDRF common content

No content at this level

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If any sub-headings are required.

3.06.05.01 Claimed shelf-life

Folder name: 3.06.05.01-ClaimedShelf-life

IMDRF common content

Contains details and evidence supporting the claimed shelf-life of the IVD medical device components (for example reagents, calibrators/reference materials, control material, any other components susceptible to degradation). Information provided in this section should include:

a) A description of recommended environmental conditions for storage of the IVD medical IVD medical device (for example temperature, pressure, humidity, light conditions)
b) A statement of the claimed shelf-life indicated as a period of time or any other means of appropriate quantification

c) An indication of the packaging used in any studies conducted in support of the shelf-life. If the packaging used in the studies differs from the final device packaging, a discussion of why the evidence can be consider valid in support of the claimed shelf-life
d) A description of the simulated transport conditions that the IVD was exposed to before the start of shelf-life studies
e) A justification of the selection of the studies performed
f) A summary of the evidence that falls within this category
g) A discussion and a conclusion to support why the evidence presented is sufficient to support the claimed shelf-life.

Or

h) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject device.

IMDRF Health Canada content

For devices that do not have an expiration period (for example electromedical equipment or other devices of multiple use), information regarding the estimated mean “lifetime”. This mean “lifetime” can be indicated as number of procedures to be performed with the device and/or its accessories, as a period of time or any other means of appropriate.

For shelf-life testing of IVDs, both a stability protocol and a stability report must be included. The protocol must contain at a minimum a protocol number, revision number and date, claimed and tested use and storage conditions, observation time points, replicate number, time of baseline observations relative to stress conditions, a description of the data analysis, acceptance criteria to be met, and a description of the testing panel.

Health Canada guidance

Stability studies are required to demonstrate that the characteristics and performance of the IVDD shall not deteriorate under normal use to such a degree that the health or safety of a patient, user, or other person is adversely affected. For shelf-life, testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be

consecutive lots). If the device has multiple components, calibrators, and/or controls that are stored separately, the shelf life studies are required for each of the components.

Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. A minimum of 6 months real time data is required at the time of the licence application.

It is suggested that a Stability Evaluation Synopsis Table be provided with a summary of the shelf-life, in-use and shipping studies.

For amendment applications involving a modification to a licensed IVDD, if the stability claim(s) are unchanged, this should be stated. If the stability claim(s) are modified, an explanation should be provided along with supporting data. The explanation should include the original stability claims and the rationale for the change(s).

If an amendment application is for a shelf-life extension, the stability protocol(s) must be provided and clearly identified as being changed or unchanged from the original protocol. If a modification or deviation from the stability protocol occurred, a clear explanation is required.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.05.01.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.05.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.05.01.01.01 Summary

Folder name: 3.06.05.01.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.05.01.01.02 Full report

Folder name: 3.06.05.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.05.02 In use stability

Folder name: 3.06.05.02-InUseStab

IMDRF common content

Contains details and evidence supporting the stability during actual routine use of the IVD medical device (real or simulated), including all applicable components (for example reagents, reaction cartridges). This may include open vial stability and/or, for automated instruments, onboard stability. Information provided in this section should include:

a) A description of recommended environmental conditions for use of the IVD medical device (for example temperature, pressure, humidity, light conditions)
b) A justification of the selection of the studies performed

c) A summary of the evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

IMDRF Health Canada content

For devices that do not have an expiration period (for example electromedical equipment or other devices of multiple use), information regarding the estimated mean “lifetime”. This mean “lifetime” can be indicated as number of procedures to be performed with the device and/or its accessories, as a period of time or any other means of appropriate quantification.

Health Canada guidance

This section should provide information on in use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability and/or calibration stability.

Classification

New licence applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgement is required to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.05.02.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.05.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – Required for each study or test presented in this section.

3.06.05.02.01.01 Summary

Folder name: 3.06.05.02.01.01–Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.05.02.01.02 Full report

Folder name: 3.06.05.02.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.06.05.03 Shipping stability

Folder name: 3.06.05.03-ShippingStab

IMDRF common content

Contains details and evidence supporting the tolerance of IVD medical device, or if provided separately, the components (for example reagents, calibrators/reference materials) to the specified or expected shipping conditions. Information provided in this section should include:

a) An indication of environmental conditions for correct shipment of the IVD medical device (temperature, pressure, humidity, light conditions, mechanical protection etc.)
b) A justification of the selection of the studies performed
c) A summary of the evidence, covering shelf-life period, that falls within this category
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

IMDRF Health Canada content

Shipping stability should contain details and evidence supporting the tolerance of device components to the anticipated shipping conditions.

Health Canada guidance

Testing should be performed on at least one lot and may be performed under real and/or simulated conditions. Evidence that the IVDD is stable under variable shipping temperatures, i.e., freezing temperature (-20°C) and extreme heat defined as greater or equal to 37˚C, should be provided.

Alternatively, evidence that the IVDD is not exposed to temperature(s) outside the recommended storage range during shipping may be submitted. This can be achieved by providing evidence that the packaging is able to maintain the device at the recommended storage temperature when exposed to variable temperature, i.e., freezing temperature (-20°C) and extreme heat defined as greater or equal to 37˚C.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.06.05.03.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.06.05.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf

- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.06.05.03.01.01 Summary

Folder name: 3.06.05.03.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.06.05.03.01.02 Full report

Folder name: 3.06.05.03.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section

3.07 Analytical performance and other evidence bibliography

Folder name: 3.07-AnalyticalPerformanceandOtherEvidenceBibliography

IMDRF common content

a) A listing of published studies relevant to the context of this chapter that involve this specific IVD medical device (for example analytical specificity, analytical sensitivity)
b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements
c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application

Or

d) A statement that no literature related to the IVD medical device was found

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.08 Other evidence

Folder name: 3.08-OtherEvidence

IMDRF common content

Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter. For example, for tests performed to ensure the

safety and/or performance of the IVD medical device that are not delineated in the rest of the Chapter 3. In addition:

a) Describe the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test
b) A justification of the selection of the studies performed.
c) A summary of the evidence that is being submitted under this heading
d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application.

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this Chapter

3.08.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.08.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a storage and validation test are being included, the application would include two subfolders:

- a custom folder named “3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28” containing two subfolders with the appropriate files:
    - 1-Summ
        - TR1525Summ.pdf
    - 2-Report
        - TR1525Report.pdf
- a custom folder named “3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29” containing:
    - 1-Summ
        - TR4584Summ.pdf
    - 2-Report
        - TR4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section.

3.08.01.01 Summary

Folder name: 3.08.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study/test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence

3.08.01.02 Full report

Folder name: 3.08.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study/test presented in this section.

Chapter 4: Clinical evidence

Folder name: 4-CLINICAL

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

4.02 Overall clinical evidence summary

Folder name: 4.02-OverallClinicalEvidenceSumm

IMDRF common content

a) This should be a brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (for example well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review, post market data from another jurisdiction or from a marketed device)) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section.

b) If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical, technical and biological characteristics of the two devices, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance

c) A discussion of the clinical evidence considered for the IVD medical device and support for their selection (that is, what type of evidence was considered and why they were or were not used)

d) Discussion to support why the evidence presented is sufficient to support the application

Note: Human factors testing that include patients should be included here.

IMDRF Health Canada content

a) Provide the Investigational Testing Authorization reference number for any clinical trials conducted under an Investigational Testing Authorization in Canada.
b) If applicable, provide the clinicaltrials.gov reference number for any clinical studies registered with clinicaltrials.gov.

If no clinical evidence is being provided, discuss why this is acceptable.

Health Canada guidance

The clinical performance studies used to establish the safety and effectiveness of the device should be presented to support the performance for each claimed indication for use.

The study protocol should include the testing algorithm, the population tested, the operator performing the test, the type of samples used, the site of the studies, the principal investigators, and a description of any panels used. A description of the statistical methods and rationale should also be provided.

The IVDD should be tested against a reference standard, method, or test, having a true clinical status, if known. If the reference is a commercial assay, it should have a valid Canadian licence, and the complete name(s) of the device(s) and the licence number(s) should be provided. If there is no Canadian licensed test, you are encouraged to contact the Medical Devices Directorate for further guidance.

Results from studies, conducted with samples representative of the specific population, under conditions similar to the conditions of use and conducted by the intended user, should be submitted in support of the clinical performance of the IVDD. These could include, for example, prospective studies conducted in a donor population, or in populations prevalent with a specific clade or strain of the agent.

Classification

New and amendment applications: Required

4.02.01 Expected values/reference ranges

Folder name: 4.02.01-ExpectedValues-ReferenceRanges

IMDRF common content

This section should include information on what values to expect in healthy normal patients versus affected patients.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

4.02.02 Clinical evidence evaluation report

Folder name: 4.02.02-ClinicalEvaluationReport

IMDRF common content

a) A clinical evidence evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the IVD medical device
b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert

Classification

New and amendment applications: Optional

4.02.03 IVD medical device specific clinical studies

Folder name: 4.02.03-DeviceSpecific

IMDRF common content

No content at this level

Clinical study information under this heading should be grouped by study

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If any sub-headings are required.

4.02.03.01 Study description, protocol #, date of initiation, date of completion

Folder name: 4.02.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this

Level 3: EU Pilot Study, CT4203, 2010-10-10
- Level 4: Clinical Study Summary
- Level 4: Clinical Study Report

Level 3: NA Controlled Study, CT4584, 2011-01-23
- Level 4: Clinical Study Summary
- Level 4: Clinical Study Report

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary first followed by the Full Report second).

Further, as described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a pilot study and a controlled pivotal study are being presented, the application would include:

- a custom folder named “4.02.02.01 -EU Pilot Study, CT4203, 2010-10-10" containing:
    - 1-Summ
        - CT4203Summ.pdf
    - 2-Report
        - CT4203Report.pdf
- a custom folder named “4.02.02.02 -Pivotal Study, CT4558, 2012-12-10" containing:
    - 1-Summ
        - CT4558Summ.pdf
    - 2-Report
        - CT4558Report.pdf

Further guidance on the content of these files is provided in the headings that follow.

Classification

New licence applications: Conditionally required – This is required for each study/test presented in this section.

Amendment licence applications: Conditionally required -Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

4.02.03.01.01 Clinical study summary

Folder name: 4.02.03.01.01-Summ

IMDRF common content

a) A summary of the specific study described in the custom heading above that includes:

i. The key characteristics of the study (for example title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, statistical design, interpretation of design, number of patients, inclusion/exclusion criteria)

ii. Summary of the results of the analysis

iii. Summary of conclusions related to the endpoints

Notes:

i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical study summary.
ii. The sponsor/applicant should explicitly state whether the data are sex-, gender-, age-, race-, and ethnicity-disaggregated. If the data are not disaggregated, the sponsor/applicant should provide a rationale why.

Health Canada *g*uidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for Medical Device Applications guidance.

Classification

New licence applications: Conditionally required – A comprehensive summary is required for each study/test presented in this section.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

4.02.03.01.02 Clinical study report

Folder name: 4.02.03.01.02-StudyReport

IMDRF common content

a) A clinical study report of the specific study described in the custom heading above

Notes:

i. The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results.
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical study report.

Classification

New licence applications: Conditionally required – A comprehensive full report is required for each study/test presented in this section.

Amendment licence applications: Conditionally required – Not required if clearly not applicable to the amendment. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

4.02.04 Clinical literature review and other reasonable known information

Folder name: 4.02.04-LitReview-OtherKnownInfo

IMDRF common content

a) Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or performance of the IVD medical device
b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements.

Or

c) A statement that no literature related to the IVD medical device was found

Notes:

i) The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject IVD medical device
ii) Please see Chapter 2.07 for Post-Market Study Plans

Classification

New and amendment applications: Conditionally required – When applicable to submission

Health Canada guidance

Include a discussion and a conclusion to support why the evidence presented is sufficient to support the application. If information within a publication is being submitted as key evidence of safety or effectiveness, a summary of the relevant data should be provided.

4.04 Investigators sites and IRB contact information

Folder name: 4.04-InvestigatorsSites-IRBContactInfo

IMDRF Health Canada content

List the clinical study sites including the name, description, and address.

Classification

New and amendment applications: Required

4.05 Real world data (RWD)

Folder name: 4.05-RWD

IMDRF common content

Where applicable, other clinical experience data/real world data (including device registries, post-market studies conducted in other jurisdictions)

Classification

New and amendment applications: Optional

4.07 Other clinical evidence

Folder name: 4.07-OtherClinicalEvidence

IMDRF common content

Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Classification

New and amendment applications: Conditionally required – When applicable to submission

Chapter 5: Labelling and promotional material

Folder name: 5-LABELLING

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

5.02 Product and package labels

Folder name: 5.02-Product-PackageLabels

IMDRF common content

Samples of the primary and secondary packaging labels.

Notes:

i. Do not include shipping labels.
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device.

IMDRF Health Canada content

All labelling must comply with sections 21 to 23 of the Medical Devices Regulations.

Consult the guidance for the labelling of in vitro diagnostic devices.

Health Canada guidance

While draft labelling may be provided initially in the licence application, final labelling will be required before a licence is issued.

The statements of indications for use and/or intended use must be clearly stated in the device labelling, and will be the official claims against which authorization will be assessed. All expressed or implied claims made elsewhere in the labelling (such as instructions of use, advertising, or promotional material) must be consistent with the official statement.

Indicate in the labelling if the labelling material covers components or devices not currently licensed in Canada.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If applicable to the amendment.

5.03 Package insert and instructions for use

Folder name: 5.03-PackageInsert-InstructionsforUse

IMDRF common content

Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable.

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device.

IMDRF Health Canada content

a) All labelling must comply with sections 21 to 23 of the Medical Devices Regulations.
b) Consult the guidance for the labelling of in vitro diagnostic devices.
c) Package inserts must include all relevant information, including a summary of the performance characteristics.
d) The current version and date of the instructions for use must be stated.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If applicable to the amendment.

Health Canada guidance

For amendments or new license applications for devices based on previously licensed devices, provide red-line versions comparing the current IFU to the IFU of the last submission. Clearly document the revision history, indicating all revisions made.

5.04 e-Labelling

Folder name: 5.04-e-labelling

IMDRF common content

In addition to the e-labelling itself, the following should be provided:

a) For eligible IVD medical devices and Software as a Medical Device, the applicant needs to identify which form of e-labelling is being used (for example electronic storage system or built-in system, website)

b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here

c) When IFUs are requested, a description of the procedure and operations on providing these IFUs

d) Written information for users on the web page identifying where the IFU and further information can be found in relevant languages

e) A description on how the e-labelling requirements for the website have been met

f) If a video/app is available to demonstrate how the test is intended to perform and be interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.

IMDRF Health Canada content

For devices that are not sold to the general public, IFUs may be provided as downloadable from the internet and/or on electronic data storage devices, for example compact disc, digital video disc, USB flash drive, etc. The electronic label or URL must accompany the device at the time of sale and/or delivery and be displayed in a manner that alerts the user to its purpose. A Letter of Attestation must also be included with the application. Refer to the guidance for the labelling of in vitro diagnostic devices for additional information.

If a video/App is available as described in f) above, the video should be available in both French and English.

Classification

New and amendment applications: Optional

5.05 Patient labelling

Folder name: 5.05-PatientLabelling

IMDRF common content

Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver.

Classification

New and amendment applications: Conditionally required – If applicable for the device

5.06 Technical and/or operators manual

Folder name: 5.06-Technical-OperatorManual

IMDRF common content

Labelling directed to the technical users and operators of IVD medical devices focusing on the proper use and maintenance of the IVD medical device.

Classification

New and amendment applications: Conditionally required – If applicable for the device

5.07 Product brochures

Folder name: 5.07-ProductBrochures

IMDRF Health Canada content

Draft product brochures available at the time of application.

Classification

New and amendment applications: Conditionally required – If applicable for the device

5.08 Other labelling and promotional material

Folder name: 5.08-OtherLabelling-PromotionalMaterial

IMDRF common content

Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Individual jurisdictions may have their own regulations or requirements regarding other labelling elements or advertising and promotional materials. If necessary, this section can be used to address jurisdiction-specific regulations or requirements involving other labelling elements other than those described elsewhere in this section, including advertising and promotional materials.

Health Canada guidance

Include any other relevant labelling or promotional material that does not fit in any other folder.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this chapter

Chapter 6: Quality management system

Folder name: 6-QMS

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

6.12 Production and service controls

Folder name: 6.12-Production-ServCtrls

IMDRF common content

ISO 13485 Elements: SOPs and device specific documentation implementing sub clause 7.5

IMDRF Health Canada content

a) Detailed manufacturing flow diagram
b) Summary of in-process acceptance activities for subject device
c) Process Validation Master Plan
d) List of processes that have not been validated

e) For each process validation considered critical to the safety and effectiveness of the device:
   i. Protocols/procedures for the validated process
   ii. Process validation report
   iii. The procedures for monitoring and controlling the process parameters of a validated process should be fully described
   iv. State the frequency of re-validation

Note:

a) Manufacturing flow diagram is required to describe the methods used in, and quality controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Sufficient detail must be provided to enable the judgement of the appropriateness of the quality controls in place.
b) If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. If the information is identical for a number of sites, this should be stated.

Health Canada guidance

Details of the lot release program including panels tested, acceptance criteria, participation in proficiency testing programs etc. should be provided.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If applicable to the amendment

6.15 Device-specific quality plan

Folder name: 6.15-DeviceSpecificQualityPlan

IMDRF Health Canada content

The review requirement for a quality plan is not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan should specify “which processes, procedures

and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract…" This information may be provided in an application in the form of a flow chart, process may, document matrix, table or text description. A quality plan specific for the subject device should link device requirements to the processes, resources and projects used by the manufacturer in producing that device.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If applicable to the amendment

6.17 Other quality system information

Folder name: 6.17-OtherQualitySystemInformation

IMDRF common content

Heading for other information that may be important to the submission but that does not fit in any of the other headings.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this Chapter