Class 4, in vitro diagnostic devices (IVD), new and amendment applications

On this page:

1 - Regional Administrative

Folder name: 1-REG ADMIN

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-Cover Letter

IMDRF common content

a. The cover letter should state applicant or sponsor name and/or their authorized representative, 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.

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

Health Canada guidance

When applicable, identify the regulatory clause associated with the submission (i.e. Section 36 or Section 39 of the Medical Devices Regulations).

Classification

New and amendment applications:

- Required

1.03 - List of Terms/Acronyms

Folder name: 1.03-List of Terms-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-Application Form-Administrative Info

IMDRF Health Canada content

A copy of the relevant Health Canada Application and Fee Forms for the application - refer to this page for the most up to date forms.

Health Canada guidance

A completed and signed application form and fee form must be provided. For further information on how to complete the Health Canada Medical Device Licence form, consult the "Guidance Document - How to Complete the Application for a New Medical Device Licence".

Classification

New and amendment applications:

- Required

1.06 - Quality Management System, Full Quality System or other Regulatory Certificates

Folder name: 1.06-QMS, Full QS or Other Regulatory Certs

IMDRF Health Canada content

This subsection includes a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies CAN/CSA ISO 13485, Medical devices - Quality management systems - Requirements for regulatory purposes. Health Canada will only accept quality system certificates that have been issued by special third party auditing organizations recognized by the Minister in accordance with Section 32.1 of the Medical Devices Regulations.

Classification

New licence applications:

- Required

Amendment licence applications:

- Not required

1.09 - Pre-Submission Correspondence and Previous Regulator Interactions

Folder name: 1.09-Pre-Submission Correspondence-Previous Regulator Interactions

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 submission or pre-submissions where regulator feedback was provided
    ii. Prior submissions should include identification of submission #
    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 (i.e., clinical study applications, withdrawn/deleted/denied marketing 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 (i.e. Health Canada does not need pre-submission information relating to interactions with ANVISA).

Classification

New licence applications:

- Conditionally required - When relevant to the application.

Amendment licence applications:

- Conditionally required - When relevant to the amendment.

1.12 - Letters of Reference for Master Files

Folder name: 1.12-Letters of Reference for Master Files

IMDRF common content

Letter from any Master File owner granting access to the information in the master file. The letter should specify the scope of access granted.

Classification

New and amendment applications:

- Conditionally required - When a Master File is referenced

1.14 - Other Regional Administrative Information

Folder name: 1.14-Other Regional Administrative Info

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 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

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-General Summary of Submission

IMDRF common content

a. Statement of the device type (e.g. Tacrolimus test system, blood specimen collection device, calibrator) and name (e.g. trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (i.e. studies that are unique to the risks of this device type).
b. Summary of submission, including
    i. The type of submission (e.g. 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 (e.g., 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.

Health Canada guidance

The executive summary template developed by MEDEC may be used as a tool. This template is not mandatory for device submission to Health Canada.

Classification

New and amendment applications:

- Required

2.04 - Device Description

Folder name: 2.04-Device Description

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

2.04.01 - Comprehensive Device Description and Principle of Operation

Folder name: 2.04.01-Comprehensive Device Desc-Principle of Op

IMDRF common content

a. A general description of the device, including:
    i. A statement of the device name.
    ii. What does it detect?
    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 (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers).
    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.

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 (e.g. electrical power requirements, settings and associated allowable ranges/limits, temperature and humidity limits, number of tests per hour, sensitivity/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. If applicable, engineering diagrams/prints/schematics of the device.
d. Describe the different specimen types that can be used for this device (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant).
e. Describe the use of controls. If applicable, a list of compatible control materials or control material specifications.
f. 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.
g. 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.
h. If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material) and source (e.g. blood, bone, heart, any other tissue or cells). 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.
i. If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action.
j. 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).
k. If applicable, a listing of assays that are compatible with the instrument.
l. If applicable, a listing of compatible instruments.
m. 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.

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

Components or accessories that can be sold separately should be identified.

Health Canada guidance

With respect to (h), a list of biological materials is not normally required. Usually for an IVDD, risk associated with biological materials is mitigated in the labelling (e.g. 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-Material Specifications

IMDRF common content

a. 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-Description of Device Packaging

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 - 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.

2.04.04 - History of Development

Folder name: 2.04.04-History of Development

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.

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.

2.04.05 - Reference and Comparison to Similar and/or Previous Generations of the Device

Folder name: 2.04.05-Ref-Comparison to Similar and-or Previous Gen

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 licensed device or is based on a modification of a licensed device, a description of the modifications is required (e.g., 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. 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, e.g., 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.

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-Intended Use-Contraindications

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-Intended Use and Indications

IMDRF common content

This section should include, as appropriate:

a. Intended Use: The statement of intended use should specify what is detected and the function provided by the device (e.g. 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 (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant)
b. Intended Purpose: What is the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate?
c. Intended user: Lay person or professional?
d. Identify if the device is intended for single or multiple use
e. 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 (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended.

Note:

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 guidance.

Classification

New and amendment applications:

- Required

2.05.02 - Intended Environment/Setting for use

Folder name: 2.05.02-Intended Environment-Setting

IMDRF common content

a. The setting where the device is intended to be used (e.g. 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 (e.g. temperature, humidity, power, pressure, movement).

Classification

New and amendment applications:

- Required

2.05.04 - Contraindications for Use

Folder name: 2.05.04-Contraindications

IMDRF common content

If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile.

Note: The statement if contraindications for the device must be as presented in the labelling.

Classification

New and amendment applications:

- Required

2.06 - Global Market History

Folder name: 2.06-Global Market History

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-Global Market History

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. If the subject device is different in any way (e.g. design, labelling, specifications) from those approved or marketed in other jurisdiction, the differences should be described.
d. The month and year of market introduction 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.
e. For each of the markets listed in (a) above, and statement of the commercial names used in those markets OR a clear statement that the commercial names are the same in all jurisdictions.
f. State the date of data capture for the market history data

g. If the subject device has been the subject of any previous compassionate use and/or clinical studies this should be identified and, if applicable, relevant reference numbers provided.

IMDRF Health Canada content

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.

Note: 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 [e.g. United States Food and Drug Administration (FDA) 510k or PMA number] should be included.

The marketing history template developed by MEDEC may be used as a tool. This template is not mandatory for device submission to Health Canada.

Classification

New and amendment applications:

- Required

2.06.02 - Global Incident Reports and Recalls

Folder name: 2.06.02-Global Incident Reports-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 state 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.

Note: It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).

Health Canada guidance

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

The marketing history template developed by MEDEC may be used as a tool. This template is not mandatory for device submission to Health Canada.

Classification

New and amendment applications:

- Required

2.06.03 - Sales, Incident and Recall Rates

Folder name: 2.06.03-Sales, Incident-Recall Rates

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 x 100
    ii. Recall rate = # recalls divided by # units sold x 100

    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 (e.g. 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 (e.g. size, version)?).

Note:

i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).
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 - Other Submission Context Information

Folder name: 2.07-Other Submission Context Info

IMDRF common content

To inform special/additional data that do not fit on previous headings.

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 in any of the other headings of this Chapter

3 - Non-Clinical Evidence

Folder name: 3-ANALYTICAL PERF

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

3.02 - Risk Management

Folder name: 3.02-Risk Management

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. The summary should address
    i. Possible hazards for the IVD medical device for example, the risk from false positive or false negative results and the risk of delays in availability of results
    ii. Indirect risks which may result from IVD medical device-associated hazards, for example, risk associated with instability, which could lead to erroneous results or user-related hazards, such as reagents containing infectious agents.
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.

Classification

New and amendment applications:

- Required

3.04 - Standards

Folder name: 3.04-Standards

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.

3.04.01 - List of Standards

Folder name: 3.04.01-List of Standards

IMDRF common content

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

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.

Health Canada's Guidance Document: Recognition and Use of Standards under 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 - Required if there are standards that have been applied in relation to the amendment.

3.04.02 - Declaration and/or Certification of Conformity

Folder name: 3.04.02-Declaration and-or Certification of Conformity

IMDRF Health Canada content

The applicant is advised to prepare the Declaration of Conformity to recognized standards using Health Canada's Declaration of Conformity form. Refer to the Guidance Document: Recognition and Use of Standards under 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-A3:2014, Evaluation of precision of quantitative measurement procedures; approved guideline, acceptance criteria and a summary of the reproducibility 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. If any rationale/testing/studies is conducted in support of the submission under the heading subject, this heading is required.

3.05 - Analytical Performance

Folder name: 3.05-Analytical Perf

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

Classification

New licence applications:

- Required

Amendment licence applications:

- Conditionally required - If any sub-headings are required.

3.05.01 - Stability of Sample(s)

Folder name: 3.05.01-Stability of Sample(s)

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

Classifications

Refer to folder "3.05.01.00 - Overview" below for classification information.

3.05.01.00 - Overview

Folder name: 3.05.01.00-Overview

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 (e.g. 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 (e.g. 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 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.

3.05.01.01 - [Study description, study identifier, date of initiation, date of completion]

Folder name: 3.05.01.01-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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 Specimens

Folder name: 3.05.02-Val of Samples

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

Classifications

Refer to folder "3.05.02.00 - Overview" below for classification information.

3.05.02.00 - Overview

Folder name: 3.05.02.00-Overview

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 (e.g. 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 (e.g. 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 (e.g. 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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Metrological traceability

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

Classifications

Refer to folder "3.05.03.00 - Overview" below for classification information.

3.05.03.00 - Overview

Folder name: 3.05.03.00-Overview

IMDRF common content

Evidence that support 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. Provide 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.

Note:

a. 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.
b. 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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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

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

Health Canada guidance

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.

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

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

Classifications

Refer to folder "3.05.04.01.00 - Overview" below for classification information.

3.05.04.01.00 - Overview

Folder name: 3.05.04.01.00-Overview

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

Health Canada guidance

The reference standard or method should be the 'Gold Standard' when one exists.

If the reference method is an IVDD, it must have a valid Canadian licence. The complete name(s) of the reference device(s) and the licence number(s) should be provided.

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf

- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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

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

Classifications

Refer to folder "3.05.04.02.00 - Overview" below for classification information.

3.05.04.02.00 - Overview

Folder name: 3.05.04.02.00-Overview

IMDRF common content

A summary of evidence that support 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.

Note:

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 quantitative test is fully automated, reproducibility studies may not be relevant.

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named

to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Analytical Sensitivity

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

Classifications

Refer to folder "3.05.05.00 - Overview" below for classification information.

3.05.05.00 - Overview

Folder name: 3.05.05.00-Overview

IMDRF common content

Evidence that support 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

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. The claims should correspond with those indicated in the directions for use (Package Insert or Instructions for Use).

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File Classification

New and amendment applications:

- Conditionally required - A comprehensive full report is **required** for each study/test presented in this section.

3.05.06 - Analytic Specificity

Folder name: 3.05.06-Analytic Specificity

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

Classifications

Refer to folder "3.05.06.00 - Overview" below for classification information.

3.05.06.00 - Overview

Folder name: 3.05.06.00-Overview

IMDRF common content

Evidence that support 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, interference studies involve adding the potential interferent to the positive and negative samples and determining any bias of the test parameter relative to the control sample to which no interferent 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:

a. substances used for patient treatment (e.g. therapeutic drugs, anticoagulants, etc.);
b. substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins, biotin, foods, mouthwash, personal care products, etc.);
c. substances added during sample preparation (e.g. preservatives, stabilizers);
d. substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);
e. analytes of similar structure (e.g. 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 (e.g. 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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf

- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-High Dose Hook Effect

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

Classifications

Refer to folder "3.05.07.00 - Overview" below for classification information.

3.05.07.00 - Overview

Folder name: 3.05.07.00-Overview

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

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Measuring Range

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

Classifications

Refer to folder "3.05.08.00 - Overview" below for classification information.

3.05.08.00 - Overview

Folder name: 3.05.08.00-Overview

IMDRF common content

Evidence that support 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 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. The claims should correspond with those indicated in the directions for use (Package Insert or Instructions for Use).

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- -TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Val of Assay Cut-off

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

Classifications

Refer to folder "3.05.09.00 - Overview" below for classification information.

3.05.09.00 - Overview

Folder name: 3.05.09.00-Overview

IMDRF common content

Evidence that support 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; and
c. statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define gray-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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Val of Assay Procedure

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

Classifications

Refer to folder "3.05.10.00 - Overview" below for classification information.

3.05.10.00 - Overview

Folder name: 3.05.10.00-Overview

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 (e.g. 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

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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

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 - 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.

3.06.01 - Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility

Folder name: 3.06.01-Electrical Systems

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

Classifications

Refer to folder "3.06.01.00 - Overview" below for classification information.

3.06.01.00 - Overview

Folder name: 3.06.01.00-Overview

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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

Folder name: 3.06.02-Software-Firmware

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 - 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

a. Specify the name of the software
b. Specify 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. Provide a description of the software including the 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.
d. Provide a statement about software version naming rules, specify all fields and their meanings of software version, and determine the complete version of software and its identification version used for release.

IMDRF Health Canada content

The level of concern associated with the software stated and supported.

Health Canada guidance

All performance studies must be conducted with the software version as used in the finished device.

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 (e.g. 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 - Hazard Analysis

Folder name: 3.06.02.02-Hazard Analysis

IMDRF common content

The Hazard Analysis should take into account all device hazards associated with the IVD medical device's intended use, including both hardware and software hazards.

Note:

i. This document can be in the form of an extract of the software-related items from a comprehensive risk management documentation, described in ISO 14971.
ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the IVD medical device.

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

Folder name: 3.06.02.03-SRS

IMDRF common content

The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements.

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 - Architecture Design Chart

Folder name: 3.06.02.04-Architecture

IMDRF common content

Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.

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

Folder name: 3.06.02.05-SDS

IMDRF common content

The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the requirements in the SRS are implemented.

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-Traceability Analysis

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.

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 Development Environment Description

Folder name: 3.06.02.07-Softw Life Cycle Process Desc

IMDRF common content

A summary describing 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 Verification and Validation

Folder name: 3.06.02.08-Software V-V

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

Classifications

Refer to folder "3.06.02.08.00 - Overview" below for classification information.

3.06.02.08.00 - Overview

Folder name: 3.06.02.08.00-Overview

IMDRF common content

a. Include an overview of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release.
b. Discussion to support why the evidence presented is sufficient to support the application.

OR

c. A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note:

i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.
ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical 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 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]

Folder name: 3.06.02.08.01-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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 - Revision Level History

Folder name: 3.06.02.09-Revision Level History

IMDRF common content

Revision history log, including release version number and date.

Classification

New licence applications:

- Conditionally required - When software is part of the device.

Amendment licence applications:

- Conditionally required - When relevant to the amendment.

3.06.02.010 - Unresolved Anomalies (Bugs or Defects)

Folder name: 3.06.02.010-Unresolved Anomalies

IMDRF common content

All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and performance, and any plans for correction of the problems).

Classification

New licence applications:

- Conditionally required - When software is part of the device.

Amendment licence applications:

- Conditionally required - When relevant to the amendment.

3.06.02.011 - Cybersecurity

Folder name: 3.06.02.011-Cybersecurity

IMDRF common content

Evidence to support the cybersecurity should be provided here. For example, but not limited to:

a. Cybersecurity vulnerabilities and risks analysis
b. Cybersecurity controls measures
c. Traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks

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.

3.06.02.012 - Interoperability

Folder name: 3.06.02.012-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-Disinfect Val

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

Classifications

Refer to folder "3.06.03.00 - Overview" below for classification information.

3.06.03.00 - Overview

Folder name: 3.06.03.00-Overview

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.

Note:

i. This applies most typically in 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 meter or by using a disinfection product with a Canadian 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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf

- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Human Factors

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

Classifications

Refer to folder "3.06.04.00 - Overview" below for classification information.

3.06.04.00 - Overview

Folder name: 3.06.04.00-Overview

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.

Note:

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.

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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

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

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-Claimed Shelf-life

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

Classifications

Refer to folder "3.06.05.01.00 - Overview" below for classification information.

3.06.05.01.00 - Overview

Folder name: 3.06.05.01.00-Overview

IMDRF common content

Contains details and evidence supporting the claimed shelf-life of the IVD medical device components (e.g. 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 (e.g. 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.

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 application amendments 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 application amendment 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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-In Use Stab

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

Classifications

Refer to folder "3.06.05.02.00 - Overview" below for classification information.

3.06.05.02.00 - Overview

Folder name: 3.06.05.02.00-Overview

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 (e.g. 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 (e.g. temperature, pressure, humidity, light conditions).
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 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.

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:

- 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.

3.06.05.02.01 - [Study description, study identifier, date of initiation, date of completion]

Folder name: 3.06.05.02.01-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Shipping Stab

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

Classifications

Refer to folder "3.06.05.03.00 - Overview" below for classification information.

3.06.05.03.00 - Overview

Folder name: 3.06.05.03.00-Overview

IMDRF common content

Contains details and evidence supporting the tolerance of IVD medical device, or if provided separately, the components (e.g. 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 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.

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, provided that a rationale explaining the circumstances is included, and clear warnings to that effect are placed on the outer box labels.

If applicable, evidence of stability following freeze/thaw cycles 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.

3.06.05.03.01 - [Study description, study identifier, date of initiation, date of completion]

Folder name: 3.06.05.03.01-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf

- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File 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-Analytical Performance and Other Evidence Bibliography

IMDRF common content

a. A listing of published studies relevant to the context of this Chapter that involve this specific IVD medical device (e.g. 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-Other Evidence

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

Classifications

Refer to folder "3.08.00 - Overview" below for classification information.

3.08.00 - Overview

Folder name: 3.08.00-Overview

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-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New and amendment applications:

- Optional

Report File Classification

New and amendment applications:

- Conditionally required - A comprehensive full report is **required** for each study/test presented in this section.

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-Clinical Evidence

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

Classifications

Refer to folder "4.02.00 - Overview" below for classification information.

4.02.00 - Overview

Folder name: 4.02.00-Overview

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 (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review) 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.
c. A discussion of the clinical evidence considered for the IVD medical device and support for their selection (i.e. 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.
c. 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 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 must 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 Bureau 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-Expected Values-Reference Ranges

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-Clinical Evaluation Report

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 - Device Specific Clinical Studies

Folder name: 4.02.03-Device Specific

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

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-Study Title, Identifier, Date (see below)

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 files, namely the summary and full report for the study presented. As described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions these files are to be named to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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-CT4203Synopsis.pdf
- 2-CT4203Report.pdf

A custom folder named "4.02.02.02 - Pivotal Study, CT4558, 2012-12-10" containing:

- 1-CT4558Synopsis.pdf
- 2-CT4558Report.pdf

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

Custom Folder 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.

Synopsis File Classification

New licence applications:

- Conditionally required - A comprehensive synopsis 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.

Report File 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-Lit Review-Other Known Info

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.

Note: 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

Classification

New and amendment applications:

- Conditionally required - When applicable to submission.

4.04 - Investigators Sites and IRB contact information

Folder name: 4.04-Investigators Sites-IRB Contact Info

Health Canada guidance

The site of the clinical study should be stated.

Classification

New and amendment applications:

- Required

4.05 - Other Clinical Evidence

Folder name: 4.05-Other Clinical Evidence

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

Classifications

Refer to folder "4.05.00 - Overview" below for classification information.

4.05.00 - Overview

Folder name: 4.05.00-Overview

IMDRF common content

Heading for other information that may be important to this submission but that does not fit in any of the other headings of this chapter. This section is specifically intended for studies performed to ensure the safety and/or effectiveness of the device that are not delineated in the rest of the Chapter 4.

Classification

New and amendment applications:

- Conditionally required - If any sub-headings are required.

4.05.01 - [Study description, study identifier, date of initiation, date of completion]

Folder name: 4.05.01-Study Title, Identifier, Date (see below)

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 files, 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 files are to be named

to ensure the sequence remains as described in the IMDRF ToC (i.e. Summary/Synopsis 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:

A custom folder named "3.5.01.01-Storage of serum samples (7 or 4 days), TR1525, 2017-10-28" containing:

- 1-TR1525Summ.pdf
- 2-TR1525Report.pdf

and a custom folder named "3.5.01.02-Validation of freeze/thaw cycles for serum samples, TR4584, 2017-11-29" containing:

- 1-TR4584Summ.pdf
- 2-TR4584Report.pdf

Custom Folder Classification

New and amendment applications:

- Conditionally required - This is **required** for each study/test presented in this section.

Summary File Classification

New licence 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.

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.

Report File 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.

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/Package Labels

Folder name: 5.02-Product-Package Labels

IMDRF common content

Samples of the primary and secondary packaging labels but exclusive of labels for shipping.

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 be provided in English or French, both official languages are to be available upon request.
b. Labelling for near-patient devices must also be provided in French and English

Health Canada guidance

Please note that a complete set of labelling associated with the IVDD as described in the Health Canada Guidance Document - Labelling of In Vitro Diagnostic Devices is required. Labelling will be reviewed against the requirements of sections 21, 22 and 23 of the Medical Devices Regulations.

The labelling should contain the final content as determined by the manufacturer, including the version number and date.

Classification

New licence applications:

- Required

Amendment licence applications:

- Conditionally required - If applicable to the amendment.

5.03 - Package Insert/Instructions for Use

Folder name: 5.03-Package Insert-Instructions for Use

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 be provided in English or French, both official languages are to be available upon request.
b. Labelling for near-patient devices must also be provided in French and English
c. Package inserts include a summary of clinical data
d. The current version of the instruction for use must be stated.

Health Canada guidance

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

Classification

New licence applications:

- Required

Amendment licence applications:

- Conditionally required - If applicable to the amendment.

5.04 - e-labelling

Folder name: 5.04-e-labelling

IMDRF common content

a. For eligible IVD medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website).
b. Provide details of risk management in relation to e-labelling. If this is part of the overallrisk management, refer to it here

c. A description of the procedure and operations on providing IFU's when requested
d. Provide written information for user Information on webpage where IFU and further information can be found in relevant languages.
e. Description on how the requirements detailed for the website have been met.

Classification

New and amendment applications:

- Optional

5.05 - Patient Labelling

Folder name: 5.05-Patient Labelling

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/Operator Manual

Folder name: 5.06-Technical-Operator Manual

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-Product Brochures

IMDRF Health Canada content

a. Draft product brochures available at the time of application.

b. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device.

Classification

New and amendment applications:

- Conditionally required - If applicable for the device.

5.08 - Other Labelling and Promotional Material

Folder name: 5.08-Other Labelling-Promotional Material

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 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.

6A - Quality Management System Procedures

Folder name: 6A-QMS PROCEDURES

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

6A.03 - Administrative

Folder name: 6A.03-Administrative

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

6A.03.02 - General Manufacturing Information

Folder name: 6A.03.02-General Manufacturing Info

IMDRF common content

a. Address and contact information for all sites where the IVD medical device or its components are manufactured.
b. Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component or raw material production (e.g. antigens, monoclonal antibodies), and sterilisation, will need to be provided.

Classification

New and amendment applications:

- Required

6B - Quality Management System Device Specific Information

Folder name: 6B-QMS DEVICE SPECIFIC

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

6B.05 - Device Specific Quality Plan

Folder name: 6B.05-Device Specific Quality Plan

IMDRF Health Canada content

The review requirement for a quality plan are 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 map, 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

6B.06.03 - Production and service controls information

Folder name: 6B.06.03-Production-serv ctrls

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 be 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 should provide a description of the methods used in, and 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 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.

ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.5

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

6B.08 - Other Device Specific Quality Management System Information

Folder name: 6B.08-Other Device Specific QMS info

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 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