Health Canada adapted assembly and technical guide for IMDRF table of contents submissions

Health Canada Santé Canada

Canada

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Guide technique et sur l'assemblage adapté aux présentations fondées sur la table des matières de l'IMDRF de Santé Canada

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Introduction

Purpose/overview

This guide provides Health Canada-specific instructions for assembling a regulatory submission package using the Table of Contents (ToC) structure defined by the International Medical Device Regulators Forum (IMDRF). The content was derived from the IMDRF document titled Assembly and technical guide for IMDRF Table of Contents submissions.

This document provides specific guidelines for building a ToC-based submission, including harmonized guidelines for the acceptable folder structure and file format(s).

Scope and application

This guide is intended for use in the assembly of ToC-based medical device regulatory submissions for submission to Health Canada. Use of the ToC structure applies to a number of pre- and post-market submission types as outlined in the Health Canada IMDRF applications guidance.

Guide to building a ToC-based submission

There are a number of reference documents and guides that need to be consulted when creating a ToC-based medical device submission. This section provides information about these reference documents and how to use these documents to generate a ToC-based submission.

Table of Contents reference documents

The table below lists the IMDRF reference documents. It also includes links to the Health Canada Table of Contents documents that should be used in building Health Canada submissions.

Table 1: List of ToC documents

IMDRF reference document	Description	Health Canada document
IMDRF non-in vitro diagnostic medical device regulatory submission	These documents define the heading names and hierarchy of the ToC structure. They also include detailed information about	• Class III nIVD applications content and classification guidance

Table of Contents (nIVD ToC) [IMDRF N9] or IMDRF in vitro diagnostic medical device regulatory submission Table of Contents (IVD ToC) [IMDRF N13]	the content that belongs under each heading.	• Class IV nIVD applications content and classification guidance • Class III IVD applications content and classification guidance • Class IV IVD applications content and classification guidance • Class II application content and classification guidance • Private label application content and classification guidance • Fax-back (minor change) application content and classification guidance
IMDRF assembly and technical guide for IMDRF Table of Content (ToC) submissions [IMDRF N27] **Note**: This document was published on March 20, 2019, and has since been archived. While it may provide useful historical context, applicants should refer primarily to the current document for the most up-to-date instructions on submission structure and requirements.	This document provides assembly and technical information for building ToC submissions. Regions may have additional requirements or regional specific guidance relating to the building and submission of a ToC-based submission that are included in a regional Assembly and Technical Guide (for example, transmission methods or special instructions for file transfer media).	Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions [current webpage]

IMDRF standard ToC folder structures (presented as a zip file)	This is a folder structure provided by IMDRF to replicate the hierarchy and headings of the ToC. Note: some headings have been modified from the full names defined in the nIVD and IVD ToC documents to reduce path lengths.	• nIVD Class III template [zip] • IVD Class III template [zip] • nIVD Class IV template [zip] • IVD Class IV template [zip] • Class II template [zip] • Private Label template [zip] • Fax-back (Minor Change) template [zip]
Regional classification matrices	As the IMDRF ToC documents are comprehensive in nature, not all headings are required for all submission types and/or regions. The regional classification matrices define whether a heading is required, not required, optional, conditionally required, etc. for a given submission type.	• Class III/Class IV nIVD Classification Matrix [Excel] • Class III/Class IV IVD Classification Matrix [Excel] • Class II/Fax-back (Minor Change) Classification Matrix [Excel]

Sample general process for building a ToC-based submission

This section describes one example of how an IMDRF ToC-based submission could be compiled. Other approaches may be acceptable, including using commercially available submission publishing software to generate a submission meeting the requirements.

Step 1: Download the IMDRF standard ToC folder structure

Download the required Health Canada ToC folder structure for the applicable submission (for example, Class III IVD or nIVD). See the resources and tools section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Step 2: Assemble the submission content

Consult the Health Canada application content and classification guidance relevant to submission type (see Table 1 for the list of guidance documents) and begin building the submission. Also consult the relevant Health Canada classification matrix and the folder structure below to establish the headings that require content and how that content should be organized. For further information about the classification matrices, please refer to Appendix 1 of this guide for important considerations.

Ensure the submission meets Health Canada's formatting guidelines (for example, format, folder structure, file naming conventions) by consulting the technical guidelines.

If your submission is being created from a submission previously prepared for a regulator other than Health Canada, ensure that:

- region-specific headings align with Health Canada. For more information consult the relevant classification matrix
- any content that is not relevant to Health Canada is removed
- any folders that may have been deleted for the original submission are reconsidered for inclusion in the new submission to Health Canada, based on the appropriate classification matrix
- content is current (for example, market history is up to date)

Step 3: Transmit the submission to Health Canada

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

To submit transactions via CESG, applicants must be enrolled in REP. For details on how to register and submit through REP, refer to: Regulatory Enrolment Process (REP) for medical devices. For more information about the CESG, consult the Common Electronic Submissions Gateway page.

Technical guidelines

The folder structure presented in this section reflects the hierarchical organization of the IMDRF ToC. To reduce file path lengths, some folder names have been abbreviated.

While this structure is designed to support consistency across different types of licence applications, specific content requirements may vary.

The following sections include basic guidelines for submitting a ToC-based submission.

Folder structure

The content requirements for each folder are defined by Health Canada's application-specific guidance documents, including those for Class II, III, and IV devices, private label applications, and fax-back (minor change) submissions. These documents align with the IMDRF IVD and nIVD ToC, which provide the overall folder structure.

The following example illustrates a typical folder layout for a Class II application and is intended to help applicants visualize and assemble their submissions accordingly.

IMDRF ToC folder structure tailored for a Class II licence application

- Licence name
  - 1-REG ADMIN
    - 1.01-Cover Letter
    - 1.04-Application Form-Administrative Info
    - 1.06-QMS Full QS or Other Regulatory Certs
    - 1.09-User Fees
    - 1.10-Pre-Submission Correspondence-Previous Regulator Interactions
  - 2-CONTEXT
    - 2.04-Device Description
      - 2.04.04-Ref-Comparison to Similar and-or Previous Gen
  - 5-LABELLING
    - 5.02-Product-Package Labels
    - 5.03-Package Insert-Instructions for Use
    - 5.04-e-labelling
    - 5.05-Healthcare Professional Labelling
    - 5.06-Patient Labelling
    - 5.07-Technical-Operator Manual
    - 5.08-Patient File Stickers-Cards-Implant Registration Cards
    - 5.09-Product Brochures
    - 5.10-Other Labelling-Promotional Material

Note: Heading numbers that are not required by Health Canada are excluded from the content guidance and templates (for example, 1.01 - Cover Letter is followed by 1.03 - List

of Terms/Acronyms as 1.02 - Submission Table of Contents is not required by Health Canada).

Refer to the Health Canada IMDRF ToC Folder templates file, which is a folder structure template to help facilitate the preparation of applications in the ToC format.

Important note:

- The top level folder of a submission contains all other folders and their content. The name of the top level folder should be the device name or licence or application number. If the licence or application number is available this is the preferred approach. If device names are used they are to be **limited to 15 characters**.

For example, if the device name is “2000X Ultrasound”, the folder may be named “2000X” as shown below.

The root folder should **not** contain any files; it should only contain the required sub-folders.

Folder layout including the root folder with 2000X (example device name)

- 2000X
    - 1-REGADMIN
        - 1.01-CoverLetter
            - Coverletter.pdf
        - 1.03-Listofterms-acronyms
            - ListofTerms.pdf
        - 1.04-ApplicationForm-AdministrativeInfo
            - ApplicationForm.pdf

Understanding heading classifications

The IMDRF ToC is designed to be comprehensive and adaptable across regulatory jurisdictions. As a result not all headings are required for Health Canada submissions. To guide applicants, Health Canada provides classification matrices that specify which headings apply for each submission type. This information is also included in the application content document for each submission type.

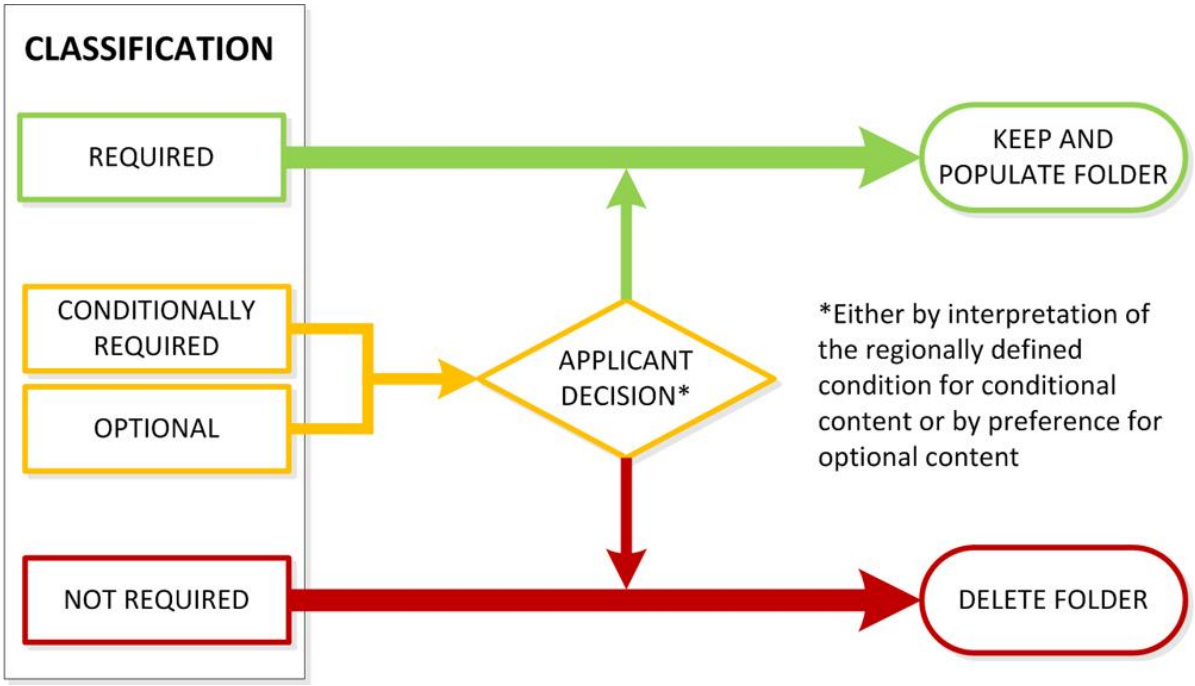
Each folder (heading) in the ToC is assigned a classification that indicates if and how it should be included in a submission, depending on the submission type and specific conditions. These classifications are summarized below:

- **R - Required.** Any folder that is established as required must not be deleted. Content must be submitted in this folder.
- **NR - Not required.** Any folder that is established as Not Required must be deleted.
- **CR - Conditionally required.** Any folder that is established as conditionally required needs a determination against the conditions by the applicant. Specific conditions are defined by Health Canada for each CR heading and can be found in the detailed content guidance.
- **O - Optional.** Any folder that is established as optional requires a decision by the applicant and then must be deleted if not populated.
- **OR - Optional but recommended.** Any folder that is established as Optional but recommended requires a decision by the applicant and then must be deleted if not populated.

Note: A brief statement may be required when a section is not included. Refer to Appendix, Statements of not applicable for further information.

With this in mind, Figure 3 below depicts many of the classifications that can result in a folder being required or not required within the submission.

Figure 1 - Classifications defined in the classification matrix (rectangles) can lead to content being required or not required in a particular submission (ovals).



This figure shows some classifications that indicate whether a folder is required in a submission, and what to do with that folder.

Classification:

- Required:
  - Keep and populate folder
- Conditionally required:
  - Applicant decision
    - Keep and populate folder **or**
    - Delete folder
- Optional:
  - Applicant decision
    - Keep and populate folder **or**
    - Delete folder
- Not required:
  - Delete folder

Applicant decision means either by interpretation of the regionally defined condition for conditional content or by preference for optional content.

Folder naming convention

The folders in the provided templates will be numbered and named per the ToC requirements, with the exception of the custom headings which are to be numbered and named as defined by the user. Specifically, in the Health Canada IMDRF Folder Structure Template – these folders appear with "[Custom]" in the folder name and should be adapted to describe identifying study details (for example [Study description, study identifier, date of initiation])). The character count for the [Custom] or [Trial Details] folder names should be **no more than 50 characters (including the section number).** Abbreviations in folder names are expected and acceptable.

Note: Restrictions in file and folder naming exist to ensure maximum allowable system file path lengths are not exceeded. Applicants should be aware that computer operating systems have limitations and are requested to keep filenames and pathnames in submissions as short as possible.

The final digit of the heading number should be revised as appropriate to ensure appropriate sequential presentation of the custom folders when more than one study is being included.

For example, for the Physical and Mechanical Characterization heading, the first custom study folder should be named “3.05.01.01[Study description, study identifier, date of initiation]” and the second custom study folder should be named “3.05.01.02[Study description, study identifier, date of initiation]”. The sequence numbering should use 2 digits (for example 3.05.01.01 … 3.05.01.10).

File format and naming

Portable document format (PDF) files are the preferred file format for submissions to Health Canada. However, other formats such as Microsoft Office (.docx, .pptx, .xlsx) are also acceptable.

File formats that are **not accepted** include, but are not limited to:

- PDF documents with attachments
- Thumbnail Cache Files (Thumbs.db)
- Outlook items (.msg)
- Backup files (~*.docx)
- Image files for example (.jpeg, .bmp, .tff)
- Files containing macros (for example .docm)
- File archives (for example .zip) with the exception of cases where the submission is being transmitted by email and a zip file of the package is created for transmission. See email transmission instructions in the Health Canada IMDRF ToC for medical device applications guidance.

The applicant should create all PDF files directly from the source documents whenever feasible rather than creating them by scanning. **PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as a Word document, and thus should be avoided if at all possible.** Scanned documents, particularly tables and graphs, are more difficult to read and do not allow the reviewers to copy and paste text. For any scanned document, you should perform optical character recognition (OCR) so that the text is searchable. Check to see that the content has been correctly converted by: (1) highlighting an area of text and (2) searching for a word or phrase. If the word or phrase is not returned in the search, then the OCR did not recognize the text. We recognize that OCR may not be feasible in some cases for documents with figures and images.

Most file names are user defined, with a limitation of **50 characters (including the file extension and section number).** File names should be meaningful and provide some indication of their content. When multiple files are considered necessary in a given folder, file naming methods should ensure that the files are presented in their intended sequence. For example, in folder named “2.04.01-Comprehensive Device Description & Principle of Operation” the files would appear as:

- 2.04.01.00-Comprehensive Device Description and Principle of Operation.pdf
- 2.04.01.01-Engineering drawings.pdf

IMDRF headings are captured one to one with folders in the folder templates.

Note: Restrictions in file and folder naming exist to ensure maximum allowable system file path lengths are not exceeded. Applicants should be aware that computer operating systems have limitations and are requested to **keep filenames and pathnames in submissions as short as possible.** Spaces in folder or file names should be avoided. If improved readability is needed, use underscores (_) or CamelCase formatting—where multiple words are joined without spaces and each new word starts with a capital letter (e.g., FileName, DeviceIdentifier).

The folder templates and file naming specifications have been established in an effort to ensure submissions can be received and stored without reaching the operating system limits. We recommend that applicants examine the length of the entire pathname (i.e. all nested folders and file name and file extension) prior to transmission to verify the path length is **200 characters or less.**

File and submission size limitations

No individual PDF file in the submission should exceed 100 MB. Multiple documents provided as a single PDF file is not acceptable.

The entire submission should not exceed 4GB to ensure acceptance.

Document security

Files should not have any additional security settings, specifically:

- Files should not have password protection, restricted access, Digital Rights Management (DRM), or Information Rights Management (IRM). preventing the file

from opening. Files with these settings may be blocked by our organization's security policies, preventing us from accessing them.

- Files should be set to allow printing, selecting text and graphics, and adding or changing notes and form fields.

Bookmarking in PDF files

It is also important that PDF files be properly structured, with a properly bookmarked internal table of contents. The following are recommended as good structuring practices:

- Documents of ten pages or more should have their own internal table of contents.
- When creating bookmarks, the magnification setting should be set to Inherit Zoom so that the destination page displays at the same magnification level that the reviewer is using for the rest of the document.
- Sections, subsections, tables, figures and appendices should all be bookmarked.
- Attachments to PDF files should be avoided.
- Too many levels of bookmarks are inefficient. In most instances, three levels of bookmarks should be sufficient. For example:
    - 1 Heading
        - Subheading
            - Sub-subheading

We recognize that bookmarks are generated automatically from document headings; nevertheless, we recommended that they be kept concise.

Set the navigation tab to open to "Bookmarks Panel and Page." This sets the initial document view when the file is opened. If there are no bookmarks, set the navigation tab to "Page Only." Page Layout and Magnification should be set to "Default."

Hyperlinking in PDF files

Hyperlinks are used to improve navigation through individual PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text, or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text. Hyperlinks throughout the body of the document to supporting annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency.

Hyperlinks between documents are acceptable but care must be taken in creating the links between different documents so that they will function once the application is received (the use of relative linking is recommended). It is the applicant's responsibility to ensure that hyperlinks are functioning. Links must also include references to the specific section or page in the event the link is broken.

Granularity rules

There are no limitations on the number of files per heading within the submission, however, the following guidelines should be considered.

1. Efforts should be made to draft documents that concisely communicate the content described in the Health Canada's application-specific guidance documents rather than simply including existing documentation that contains superfluous information not required for the particular heading. For example, including a number of Material Safety Data Sheets within "2.04.01 - Comprehensive Device Description and Principle of Operation" is less helpful than summarizing the specific details of relevance to this heading.
2. When multiple files are considered necessary, file naming methods should ensure that the files are presented in their intended sequence. For example, in the folder named "2.04.01-ComprehensiveDeviceDesc-PrincipleofOp" the files would appear as:
    - 2.04.01.00- ComprehensiveDeviceDesc-PrincipleofOp.pdf
    - 2.04.01.01-Engineeringdrawings.pdf

Pagination

Pages of the submission should be numbered in such a manner that information can be easily referenced by page number. Pagination should be applied to each document. This may be done by numbering the pages within a section or chapter (for example, 2.04.01-1, 2.04.01-2).

Health Canada has a defined set of validation rules described in the Validation rules for regulatory transactions in non-eCTD format guidance document. Free validation tools are available from some regulatory submission software providers. Applicants are encouraged to validate their submission using these rules prior to submission to Health Canada.

Important note:

Errors relating to validation Rule “C05-Naming Syntax” should be ignored when they are the result of the use of characters required for the ToC submission that do not meet International Council for Harmonization (ICH) (For example upper case letters, “.”).

The 200 character path length limitation defined in this validation rule remains a requirement for ToC submissions.

Appendix: Helpful hints

The classification matrices and heading class

As the ToC documents are comprehensive in nature, not all headings are required for all submission types. The ToC documents are therefore intended to work together with a classification matrix.

What are the classification matrices?

The classification matrices are tables that define the class of each heading in the ToC (for example required (R), not required (NR), conditionally required (CR), optional (O), optional but recommended (OR)).

Supported submission types are listed separately within the matrix. For example, Table 2 shows the first four headings of Chapter 1 for a new Class III submission. Please note that if the heading is CR the condition will be described in the condition column.

Table 2: Example classification matrix

Code (TOC level)	Display name	Class III new	
		Classification	Condition
Chapter 1: Regional administrative			
CH1.01	Cover Letter	R	
CH1.02	Submission Table of Contents	NR	
CH1.03	List of Terms/Acronyms	R	
CH1.04	Application Form/Administrative Information	R	

Where can the classification matrices be found?

The classification matrices are available on the Resources, tools and classification matrices section on the Health Canada IMDRF Table of Contents for medical device applications guidance page.

How do I use the classification matrix with the ToC?

The following describes the general steps in using the classification matrices:

1. Establish the submission type and verify that the submission type is within the scope of the current classification matrix.
2. Build your submission structure based on the guidance provided for that submission type. Any headings that are marked not required (NR) should not be included in the submission. Any headings that are conditionally required (CR) need to be considered within the context of the device type and or any conditions stipulated in the classification matrix. The applicant must address **all** required (R) headings in the submission.

For example, a new Class IV submission requires only a few elements of Chapter 6. In this case, the classification matrix is shown in Table 3.

Chapter 6 would only contain three or four headings (highlighted in green), depending on whether or not the condition for the CR classified heading establishes the heading is relevant to the submission.

Table 3: New NIVD class IV submission classification matrix excerpt

Code (TOC level)	Display name	Class IV new	
		Classification	Condition
Chapter 6 – Quality management system			
CH6.1	Chapter Table of Contents	NR	
6.01	Cover Letter	NR	
6.02	Chapter Table of Contents	NR	

6.01	Cover Letter	NR	
6.02	Chapter Table of Contents	NR	
6.03	Product Descriptive Information	NR	
6.04	General Manufacturing Information	NR	
6.05	Required Forms	NR	
6.06	Quality management system	NR	
6.07	Management responsibilities	NR	
6.08	Resource management	NR	
6.09	Planning of Product Realization and Customer Related Processes	NR	
6.10	Design and development	NR	
6.11	Purchasing	NR	
6.12	Production and service controls	R	
6.13	Control of monitoring and measuring equipment	NR	
6.14	QMS measurement, analysis and improvement	NR	
6.15	Device Specific Quality Plan	R	
6.16	Quality management system verification document	NR	
6.17	Other Quality System Information	CR	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.

Important note:

Each classification matrix is developed based on a variety of sources including laws, directives, regulations, guidance documents, etc. When any requirements are conflicting between the classification matrix and these sources, the source requirement will take precedence.

Custom headings

The ToC has been developed with flexibility to allow for use of the same structure across a variety of risk classes. One particular sub-structure is repeated throughout the document. This structure includes a parent heading, a custom child heading for each specific study/piece of evidence, and a summary and full report grandchild heading. For example, "Physical and Mechanical Characterization" is structured as shown below.

Table 4: Example ToC content – physical and mechanical testing

Heading name	Content description
Physical and Mechanical Characterization	Parent heading containing an overview file that concisely summarizes all studies related to physical and mechanical testing.
Study description, study identifier, date of initiation	This is a custom heading based on the particular study described below – **no content at this level**
Summary	A summary of the specific study described in the custom heading above.
Full Report	The test report for the test described in the custom heading above.
Heading name	Content description

Important note:

- In the case where there are many studies under a particular heading, the studies should be presented sequentially under the parent heading as shown in the example below.

Example of folder structure for implementation

Example folder structure for Chapter 3 with custom headings and summary/full report PDFs

- 3.05.01-Physical-Mechanical
  - Overview.pdf
  - Component A Fatigue Test, MT4203, 2010-10-10
    - 1-Summ
      - MT4203Summ.pdf
    - 2-Report
      - MT420report.pdf
  - Assembly B Compatibility Test, MT4584, 2011-01-23
    - 1-Summ
      - MT4584Summ.pdf
    - 2-Report
      - MT4584Report.pdf

The content at the parent heading level that contains the overview file is intended to provide a concise summary of the evidence presented in the subchapter and helps ensure clarity and traceability, especially when multiple studies are submitted.

The overview should be a high level description, for example:

Physical and mechanical characterization (hip liner example):

Based on the risks associated with hip liner, the following evaluations were considered:

- wear testing
- lever-out testing
- …

However, because the locking mechanism and overall geometry remain identical to previous versions, it was not considered necessary to repeat lever-out testing for the new design. Wear testing was deemed necessary because of the change in manufacturing processes for the UHMWPE. A copy of the previously conducted test has been included for reference and was previously reviewed under submission XYZ.

Wear testing – this testing was conducted on the largest component listed in this submission: size 36, +4mm offset according to ASTM F1714 for 10 MC. Wear results

assessed for volume and morphology and were found to be comparable to clinically proven devices tested under identical conditions.

Wear is one of the primary causes of clinical failure in hip implants. This characterization shows that the wear properties of this device are similar in volume and morphology to clinically successful devices.

Statements of not applicable

Many headings in the submission require a statement as to why the particular category does not apply for a given submission. The level of support for such statements will vary and can be presented by the categories described below.

Note: The classification matrices are the authoritative source for content being submitted. Where interpretation of the classification indicates the heading as **not required** as discussed in Figure 1, **the heading should be excluded in its entirety from the submission.**

Table 5: Descriptions and examples of categories of not applicable statements

Category	Description	Suggested action
Category 1: No relevance to the submission	In this case the information is obviously not applicable to the device. For example, evidence of biological material safety would not be required if no biological material is used in the device.	Recommendation varies by submission type and based on the heading classification. If the classification for the submission type indicates the heading to be **required**, no explanation is necessary and a statement “Not relevant to this submission” is sufficient. If the classification for the submission type indicates the heading as **not required** (either explicitly or through interpretation of the condition) **the heading should be excluded in its entirety from the submission.**

Category 2: Potential relevance to the submission but still clearly not applicable	In this case, the information may be relevant in some situations, but in the specific context it is still clearly not applicable. For example, a case where the manufacturer is changing the sterilization method but the device remains unchanged and therefore no biological safety information is provided.	Recommendation varies by submission type and based on the heading classification. If the classification for the submission type indicates the heading to be **required**, **further explanation of the specific context is required, but can be limited to a few sentences**. For example, “The change in sterilization method has no impact on the safety of the source of the biological materials which have been reviewed previously”. If the classification for the submission type indicates the heading as **not required** (either explicitly or through interpretation of the condition) **the heading should be excluded in its entirety from the submission.**
Category 3: Relevant to the submission but not included	In this case the information would be expected for the submission but has been omitted after careful consideration. For example, disassembly testing for a new modular hip implant system would typically be expected for the device type, but has been omitted.	In these cases, interpretation of the classification matrix should lead to a classification of **required**. Detailed scientific support for the decision not to conduct this testing should be presented and any relevant references provided in the submission to support the rationale.