Health Canada Santé Canada

Guidance Document

Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice - Exigence en matière d'homologation des instruments médicaux implantables fabriqués par impression 3D

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Table of Contents

1. Introduction

1.1 Overview

This guidance document is intended to aid manufacturers and regulatory representatives in preparing medical device licence applications for 3D printed medical devices. As with all Class III and IV medical devices, devices produced by additive manufacturing or 3D printing, are subject to the Medical Devices Regulations (Regulations) and require a review of submitted evidence of safety and effectiveness before a licence can be issued.

This guidance document should be read in conjunction with the Guidance Document on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-supporting-evidence-provided-new-amended-licence-applications-class-class-medical-devices-including-vitro-diagnostic.html).

1.2 Scope and application

The document provides guidance for manufacturers regarding specific evidence required to support pre-market Class III and Class IV licence applications for implantable medical devices manufactured by 3D printing processes. Considerations related to the design and manufacturing process, material controls, device testing, and labelling of 3D printed devices are included in this document. Requested information may vary in terms of content and level of detail depending on the 3D printing process (or processes) and the risk class of the finished device.

The content described in this document is to be submitted for review in addition to the general data elements listed in paragraphs 32(3) and (4) of the Regulations.

This document will not provide guidance on standalone software, custom-made devices[1], anatomical models or products made through bio-printing which incorporate viable living cells.

1.3 Policy objectives

To provide manufacturers with the necessary information to complete a medical device licence application for a Class III or IV devices manufactured by 3D printing pursuant to the Regulations.

1.4 Policy statements

All Class III and Class IV medical devices require a review of submitted evidence of safety and effectiveness before a licence can be issued.

The same evidence requirements apply to 3D printed devices as those for non-3D printed devices in terms of their characterization and evidence of safety and effectiveness, including physical and mechanical bench testing, biocompatibility testing, software validation and clinical evidence.

As part of the evidence to demonstrate the safety and effectiveness of a Class III or IV 3D printed device, manufacturers should submit the additional information outlined in this

guidance document with their application. Failure to submit the additional information with an application could result in a request for additional information under subsection 35(1) of the Regulations at any time during the review (i.e., during either the screening or review phase).

In keeping with international standards, the guidance document adopts definitions developed by the International Medical Device Regulators Forum (IMDRF) with respect to Definitions for Personalized Medical Devices.

Healthcare facilities which manufacture 3D printed implantable medical devices under their own name and distribute them outside of their own corporate entity, qualify as a manufacturer, and will be subject to all the requirements of the Regulations.

1.5 Background

Health Canada is committed to supporting the integration of 3D printed technologies into health care systems in Canada, and providing Canadians with the highest possible quality of care.

The federal government is actively working and collaborating with international counterparts to keep pace with the research and development of 3D printing. Canada's licensing approach for implantable medical devices manufactured by 3D printing is well aligned with international best practices.

Due to the fast-changing technological environment, Health Canada will continue to adapt its policy approach to 3D printing as issues on the topic evolve. This guidance document therefore represents the first phase of 3D printing policy in Canada.

2. Guidance for implementation

2.1 Information for Class III and IV 3D printed implantable medical device licence applications

The Guidance on Supporting Evidence to be provided for New and Amended Licence Applications for Class III and Class IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs), outlines the general data elements and the technical content commonly accepted in support of the safety and effectiveness of a Class III and IV device; these evidence requirements apply to all Class III and IV licence applications.

Sections 2.1 to 2.4 of this document provide recommendations for **additional information,** specifically related to 3D printing processes and the finished device, which should be included in a licence application. If a section of the licence application is not referenced in this document, then no additional evidence requirements related to 3D printing have been identified for that section.

For example, packaging is not referenced in Sections 2.1 to 2.4; however, the existing requirements for packaging as outlined in Sections (3)5.5 and (4)4.9.7 in the Guidance document on supporting evidence to be provided for new and amended licence applications for Class III and Class IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-

devices/application-information/guidance-documents/guidance-document-guidance-supporting-evidence-provided-new-amended-licence-applications-class-class-medical-devices-including-vitro-diagnostic.html) still apply.

Refer to Appendix B for further information regarding the corresponding sections of:

(i) Guidance Document: Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing, and
(ii) Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs), or
(iii) Table of Contents (TOC) folder for submission of Class III and IV licence applications

2.1.1 Device description

A description of the finished device is required, and should include photograph or drawing of the device with all functional components clearly labelled. The device description should state whether the entire device or only a component of the device is 3D printed.

In addition, for 3D printed devices, a description of the starting material should be included in this section of the licence application, including:

- reference to any relevant material standards
- the chemical composition of the starting material (including certificates of analysis where applicable), and
- identification of any additives or processing agents mixed with the starting material

The description of the 3D printing method (e.g., laser sintering, direct metal laser sintering and powder bed fusion) should be provided in addition to an overview of the printing process including post-printing processing steps. Quality control procedures should also by identified in the overview of the manufacturing process.

> e.g., A flow chart may be provided for a Class III device licence application; arrows, symbols or colours may be used to indicate QC procedures in the flow chart.

Further information related to manufacturing and quality control for Class IV device licence applications is provided in Section 2.4.

In cases where the device is patient-matched[2] rather than manufactured to pre-determined sizes, the description should include:

- an overview of the printing process from patient image acquisition to device design, printing and post-printing processing steps e.g., a flow chart may be provided for a Class III licence application and arrows, symbols or colours may be used to indicate QC procedures in the flow chart
- key design parameters
- parameters of the device that may be altered to be patient-matched, if not the entire device, and
- critical features, including the range and boundaries of dimension (i.e., location and thickness of porous features)

Further characterization of the starting material may be required in specific cases. For example, if a licence application is submitted for a raw material intended for 3D printing by a qualified dispenser. In these cases, the review of the licence application would be based on:

(i) the specific indications for use (i.e., for the fabrication of dental restoratives) which must be clearly stated on the label
(ii) the specific material-printer combination which must be clearly stated on the label, and
(iii) the worst case scenario for preclinical testing of the finished device (or range of finished devices) for which the material is intended to produce

In these cases, additional characterization of the starting material may include parameters measured prior to polymerization/fusion (as appropriate, depending on phase). For example:

- if the raw material is in solid phase: particle size and size distribution for powders or filament diameter and diametric tolerances for filaments, composition and purity (for alloys), mix ratio (for composites)
- if the raw material is in liquid phase - viscosity or viscoelasticity, pH, ionic strength, or
- if the raw material is a polymer or monomer mixture - composition, purity, water; content (if applicable), chemical structure, molecular formula and weight, percent crosslinking (if applicable), melting point

Evaluation of the parameters listed above may be considered in the determination of the suitability of the starting material for the intended finished device(s).

2.1.2 Design philosophy

For 3D printed devices, the design philosophy may include a discussion and/or regarding the choice to use 3D printing as a manufacturing process (i.e., patient-matched devices, devices with complex geometry and/or non-standard sizing).

2.1.3 Licence amendments

A licence amendment application is required when a significant change is reasonably expected to affect the safety and effectiveness of the finished device. The same criteria for determining significant changes for 3D printed devices may be applied from those outlined for non-3D printed devices; information on Health Canada's interpretation of significant change is available in Guidance for the Interpretation of Significant Change of a Medical Device (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-interpretation-significant-change-medical-device.html).

A description of the proposed modification/change is required (e.g., changes in design, performance, indications). A comparison of the subject device with the proposed modifications and the previously approved device should be provided in tabular format.

Examples of modifications related to 3D printing may include, for example, but are not limited to:

- a 3D printed component that is being added to a previously approved component (e.g., porous surface coating)

- a 3D printed component that is to be used with an existing compatible component (e.g., dental superstructures/abutments/implants)
- changes in material or material specifications
- changes to the post-processing steps (i.e., heat treatment, surface treatment) which may affect the finished device
- changes in the material-printer combination
- software-related changes which may affect the finished device

2.1.4 Marketing history/regulatory status

If the market history for the 3D printed device is not yet available or limited (i.e., the first year of sales or less), a summary of the market history for a relevant previously approved device may be provided. The market history for any comparable 3D printed components may also be provided if relevant/applicable (i.e., if the same 3D printed porous coating is used on multiple devices from the same manufacturer).

2.2 Safety and effectiveness

2.2.1 Standards

The list of standards applied, in whole or in part, in the design and manufacture of the device should be provided in the application. Reference to relevant 3D printing-related standards should be included in this list.

For those standards recognized by Health Canada, a Declaration of Conformity (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/forms/declaration-conformity-forms-medical-devices.html) may be signed. The recognition status of a given standard is subject to change over time; updates are provided on the Health Canada website.

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

2.2.2 Preclinical studies

Preclinical performance testing should be conducted on the final, finished device (subjected to all post-printing processing, cleaning, and sterilization). For each test, a detailed summary is required and should include a description of the test objective, samples tested, analysis of the worst case configuration of the test samples with respect to dimensions and features (e.g., holes, supports, porous areas), acceptance criteria with justification, adherence to international standards (where applicable), test results and a discussion/analysis of the results in terms of the test objective.

For 3D printed devices, analysis of the worst case device configuration for preclinical testing may include reference to, or a summary of:

- process-related validations which consider device size, orientation and placement within the printer build space
- process-related validations of multiple build cycles to address reproducibility and consistency in the printing process, and

- validation of powder recycling (if applicable) with consideration of potential effects on melting properties and bonding between layers.

The use of test coupons may also be appropriate to support finished device performance where the manufacturer can demonstrate that the test coupon:

- is sufficiently representative of the subject device in terms of critical design parameters (i.e., orientation, geometry, thickness, critical dimensions, smooth edges), and
- has undergone identical post-printing processing and sterilization as the final finished device

For patient-matched devices, the worst case configuration for preclinical testing should be based on the critical boundaries of design, size, and geometry of the finished device. Analysis of the worst case configuration for patient-matched devices may also include reference to, or a summary of, process-related validations which consider device size, orientation and placement within the printer build space. In addition, preclinical testing of patient-matched devices should include validation of the accuracy of the finished device reproduction from the patient images.

Specific preclinical test requirements will vary depending on the device type and additional factors such as whether the device is load-bearing, patient-matched or manufactured to standard/pre-determined sizes. In general, mechanical performance and strength testing may include, but is not limited to:

- tensile strength (ultimate tensile strength, yield strength, maximal elongation)
- flexural strength
- dynamic fatigue strength
- corrosion
- wear
- shear strength/adhesion for a coating
- compression strength, or
- bending strength

Where applicable, comparative test results for a 3D printed device and a non 3D printed previously approved device should be provided.

2.2.3 Shelf life

Additional shelf life considerations related to 3D printed devices may include:

- effects on long term material stability (with respect to inter-layer bonding and homogeneity across build layers)
- possible time-dependent changes to patient anatomy for patient-matched devices, and
- raw material shelf life (where applicable)

A rationale should be provided with the shelf life test summary to show how the shelf life testing addresses additional considerations related to 3D printing (where applicable).

For materials for which long-term stability is unknown, it is preferable to provide real-time shelf life test results.

2.2.4 Software verification and validation

For patient-matched devices, the licence application should include an overview (e.g. in the form of a flowchart) of the software-related workflow from medical image acquisition to segmentation and design manipulation for the final print preparation. With respect to specific instructions for image-acquisition parameters (e.g., supported imaging modalities, scanning parameters, image reconstruction parameters, file types, patient positioning or gating requirements), it is recommended that these parameters be clearly communicated from the manufacturer to the healthcare provider responsible for image acquisition. Upon receipt of patient images, the manufacturer should verify these parameters for acceptability prior to subsequent steps in the device design and printing process.

2.2.5 Biocompatibility tests

For 3D printed devices, evidence of biocompatibility from a previously approved (non-3D printed) device is generally not considered sufficient to support biocompatibility of 3D printed devices due to differences in the manufacturing process.

As for non-3D printed devices, biocompatibility testing should be conducted on the final, finished device as per the requirements of ISO 10993-1:2009 (please refer to Appendix B). Adherence to material standards may be noted either in a Declaration of Conformity (if the standard is recognized by Health Canada) or as part of the information provided under biocompatibility.

It may be appropriate to leverage biocompatibility test results from a previously approved 3D printed device if the same material and printing process are used in subsequent licence applications. A justification for the use of previously approved biocompatibility test results should be provided in this case.

If the licence application includes multiple 3D printed devices with identical printing/cleaning/sterilization processes, biocompatibility testing should be conducted on the worst case device. The potential for residual supportive material should also be considered in the analysis of the worst case scenario for biocompatibility.

2.2.6 Animal studies

Animal studies are generally used as supportive evidence for safety and effectiveness in humans. A 3D printed device with a novel design, material, or intended use may require animal studies. For example, animal studies could be used to support effectiveness claims related to enhanced bony ingrowth in a porous structure or coating manufactured through 3D printing.

2.2.7 Clinical studies

Device-specific clinical data may be required for a 3D printed device with a novel design, material, or intended use.

If the device design and intended use is well established for the technology type, and adequate supporting evidence has been provided in the licence application, it may be appropriate to provide clinical evidence in the form of a literature review of relevant publications from peer-reviewed scientific literature.

Where long term clinical data for 3D printed device may not be available, the clinical experience of a comparable non-3D printed device may be considered during the evaluation of safety and effectiveness of the 3D printed device. The requirement for additional device-specific clinical data is determined on a case-by-case basis during the review of the licence application.

Manufacturers may contact the Medical Devices Bureau for further guidance on the requirements for device-specific clinical data, through either informal consultation or a request for a pre-submission meeting to obtain in-depth advice or guidance on their licence application.

2.2.8 Post-printing processing, cleaning and sterilization

This section considers both the cleaning and sterilization processes related to 3D printed devices, where "cleaning" generally refers to the removal of excess starting material and/or manufacturing material residues to a level that does not affect the safety or effectiveness of the finished device. It is acknowledged that these processes will vary depending on the starting material, printing process, and design of the finished device. For example, if the 3D printed device is manufactured from metal powder, the "cleaning" validation should include consideration of the powder removal process to support the capacity of the cleaning process to remove loose powder particles.

Validation of the cleaning and sterilization processes should consider the worst case scenario in terms of residual material residues, surface area, porosity and voids in the finished device. Cleaning and sterilization challenges related to 3D printed devices may include:

- complex structures (i.e., engineered porosity, internal channels/voids/cavities with limited or no access, destructive testing may be required to support cleaning validation of 3D printed devices with complex structures)
- increased surface area
- adequate removal of supportive structures such as overhangs, protruding features, and internal features, and
- thin features prone to warping

With respect to sterilization validation, evidence should be provided to show:

- how bioburden was minimized throughout the 3D printing processes
- if the sterilization process may affect the material characteristics and device performance (e.g., one-piece solid cast device vs. 3D printed porous device), and
- if the sterilization method is appropriate for the device material

For patient-matched devices, sterilization validation should consider the worst case configuration based on the critical boundaries of design, size, and geometry of the finished device.

Any changes from methods of sterilization validation as outlined in the requirements of recognized standards should be described and justified in the sterilization validation.

2.3 Device labels, package labelling and documentation

For patient-matched devices, the manufacturing process may include multiple transfers of patient images and device design files between the manufacturer and health care professional.

Adequate labelling for device identification and design version control should be provided, while considering patient privacy and confidentiality.

Labelling of patient-matched devices may include:

- the patient's name or a suitable identifier
- anatomical location for implantation, or
- final design iteration or version used to produce the device

The expiration date for a patient-matched device may be based on the patient imaging date or the design finalization date rather than the standard methods of determining device shelf life. Changes in patient anatomy may occur between the time of imaging and surgery which could impact performance of the device. Labelling of patient-matched devices should include a precaution stating that the patient should be assessed for potential anatomical changes prior to the procedure.

2.4 Additional considerations for Class IV 3D printed implantable medical devices - process validation studies

The Class IV licence application includes a section for "Process Validation Studies". These validations may vary depending on the printing process, however they may include further details regarding evidence to support reproducibility and consistency in the printing process. This could include:

- the analysis of worst case parameters and printer performance within and across build cycles (i.e., performed as part of process-related validations which consider device size, orientation and placement within the printer build space), and
- the analysis of critical environmental conditions within the build space/volume, including in-process monitoring of build-space conditions, power of energy delivery systems, and/or test coupon evaluation

3. Contact Information

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4. Appendices

Appendix A - Glossary

3D printing (3DP)[3]:

Also referred to as "Additive Manufacturing" (AM) and defined as "a process that builds an object by iteratively building 2-dimensional (2D) layers and joining each to the layer below, allowing device manufacturers to rapidly alter designs without the need for retooling and to create complex devices built as a single piece".

Additive manufacturing (AM)[4]:

Process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies.

Health care facility:

A facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.

Health care professional:

A person who is entitled under the laws of a province to provide health services in the province.

Patient-matched medical device:

A medical device that meets the following requirements:

- it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and
- it is typically produced in a batch through a process that is capable of being validated and reproduced, and
- it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional

Note 1: A written request from an authorized health care professional may be present; but is not mandatory.

Note 2: The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.

Note 3: The design must remain within the validated parameters of the specified design envelope.

Validation:

As it applies to process validation, refers to studies which provide objective evidence of performance, adequacy, reproducibility and effectiveness of relevant procedures used in the manufacturing process.

Test coupon:

A representative sample of the material which may be suitable for process validation and/or preclinical testing.

Standalone software:

Software that visualizes, processes or analyzes a medical image or creates virtual 3D models, capable of running on general purpose computing platforms, that is not part of a hardware device.

Terminology related to printing processes as defined in ISO/ASTM 52900:2015

Binder jetting:

Additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials.

Powder bed fusion:

Additive manufacturing process in which thermal energy selectively fuses regions of a powder bed.

Material extrusion:

Additive manufacturing process in which material is selectively dispensed through a nozzle or orifice.

Build space:

Location where it is possible for parts to be fabricated, typically within the build chamber or on a build platform.

Build volume:

Total usable volume available in the machine for building parts.

Laser sintering:

Powder bed fusion process used to produce objects from powdered materials using one or more lasers to selectively fuse or melt the particles at the surface, layer upon layer, in an enclosed chamber.

Post-processing:

One or more, process steps taken after the completion of an additive manufacturing build cycle in order to achieve the desired properties in the final product.

Powder bed:

Part bed, build area in an additive manufacturing system in which feedstock is deposited and selectively fused by means of a heat source or bonded by means of an adhesive to build up parts.

Appendix B - Corresponding sections of Health Canada guidance or Table of Contents (TOC) folder structure

This table highlights the section or folder where additional information related to 3D printed medical devices is recommended, and the section or folder under which the information should be provided:

Guidance on Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing		**Corresponding Section of:** **Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs)[5]**		**Corresponding Section of:** **TOC Folder Structure[6]**
Applicable to Class III and IV Applications				
Section title	**Section**	**Class III**	**Class IV**	**Class III and IV**
Device Description	2.1.1	(3) 4.3	(4) 4.3	2.04
Design Philosophy	2.1.3	(3) 4.3.2	(4) 4.4	2.04.03 & 2.04.04
Licence Amendment	2.1.2	(3) 4.3.2	(4) 4.3.2	2.02
Market History	2.1.4	(3) 4.7	(4) 4.8	2.06
Safety and Effectiveness				
Section title	**Section**	**Class III**	**Class IV**	**Class III and IV**
List of Standards	2.2.1	(3) 5.1	(4) 5.1	3.04
Preclinical Studies		(3) 5.2	(4) 5.2	3.05
• Physical and Mechanical Bench Tests	2.2.2	(3) 5.2.1	(4) 5.2.1	3.05.01
• Software Verification and Validation	2.2.4	(3) 5.2.2	(4) 5.2.2	3.05.05.08
• Biocompatibility Tests	2.2.5	(3) 5.2.3	(4) 5.2.3	3.05.06
• Animal Studies	2.2.6	(3) 5.2.5	(4) 5.2.5	3.05.10
• Clinical Evidence	2.2.7	(3) 5.3	(4) 5.3	4

Sterilization	2.2.8	(3) 5.4	(4) 4.9.6	3.05.09
Shelf Life	2.2.3	(3) 5.6	(4) 4.9.8	3.07
Labelling	2.3	(3) 4.6	(4) 4.7	5
Sections Applicable to Class IV Applications				
Process Validation Studies	2.4	(4) 4.9.5		6B.06.03

Appendix C - References

- Guidance Document on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs)
- Guidance for the Interpretation of Sections 28 to 31: Licence Application Type
- IMDRF Final Document International Medical Device Regulators Forum, Definitions for Personalized Medical Devices
- U.S. Food and Drug Administration Guidance Document for Industry and FDA Staff, Technical Considerations for Additive Manufactured Medical Devices (2017)
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, ISO 10993-1:2009/Cor.1:2010SO 10993-1:2009

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[1] A custom-made device is one which is made to correspond with a health care professional's specific directions or needs. These devices are usually specifically produced for a particular patient or procedure.

[2] Throughout this guidance document the term patient-matched device is defined as per the IMDRF Final Document, International Medical Device Regulators Forum, Definitions for Personalized Medical Devices.

[3] U.S. FDA's 2017 Guidance Document for Industry and FDA Staff, Technical Considerations for Additive Manufactured Medical Devices

[4] ISO/ASTM 52900:2015 Standard Terminology for Additive Manufacturing - General Principles-Terminology

[5] For non-TOC applications, Class III and IV licence applications should comply with the format specified in Guidance on Supporting Evidence to be provided for New and Amended Licence Applications for Class III and Class IV Medical Devices, not including In Vitro Diagnostic Devices (IVDDs)

[6] For TOC applications – Please consult the Draft Health Canada IMDRF table of contents for medical devices applications guidance for further information regarding the structure and content requirements for applications submitted under the TOC format (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/international-medical-device-regulators-forum.html)