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DRAFT GUIDANCE FOR INDUSTRY

Guidance for Manufacturers preparing a Premarket Application Using the Summary Technical Documentation (STED) for Demonstrating Conformity to the *Essential Principles of Safety and Performance of Medical Devices*

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Health Products and Food Branch
Guidance Document

Canada

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Directive à l'intention des fabricants qui préparent une demande précommercialisation à l'aide de la Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices
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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

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 scientific justification. Alternate approaches should be discussed in advance with the relevant program 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 guidance, 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 guidances.

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1.0 Purpose

This guidance document outlines the Therapeutic Products Directorate (TPD)'s proposal to implement a pilot program and to solicit participation from the medical device industry to evaluate a proposed globally harmonized format and content for premarket application packages (e.g. for Class III and IV device licence applications).

This guidance document will provide medical device manufacturers electing to participate in the pilot program with:

- administrative instructions on the participation in the pilot program
- description of Canadian-specific evidence not covered by the harmonized format and content document but required to support a Class III or Class IV device licence application
- tables that compare the difference between the draft globally harmonized format and content document and the Canadian regulatory submission requirements for Class III and Class IV device licence applications.

2.0 Background

This pilot program has its origins in the recommendations of the Global Harmonization Task Force (GHTF), Study Group 1. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and regulated industry. The GHTF mandate is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices to promote technological innovation, and facilitate international trade.

The GHTF identified a need to harmonize the documentation of evidence of conformity to regulatory requirements. Differences in documentation requirements necessitate additional work for the same device in different jurisdictions, increase costs and pose barriers to the timely international access to medical devices. To minimize the regulatory burden on manufacturers associated with current conflicting format and content requirements of different regulatory authorities, Study Group 1 of GHTF developed the *Summary Technical Documentation* (STED).

The *Summary Technical Documentation* (STED) is an internationally harmonized format and content document for premarket applications and is based on conformity to the *Essential Principles of Safety and Performance of Medical Devices* (hereby referred to as the Essential Principles). The STED is available at www.ghtf.org under Study Group 1- Working Drafts.

The Essential Principles are a GHTF-derived list of both general and specific safety and performance recommendations for medical devices and are similar to the general Safety and Effectiveness Requirements (Sections 10 to 20) of the Canadian *Medical Devices Regulations*. The Essential Principles document is available under www.ghtf.org under Study Group 1 - Final Documents.

A copy of the *Medical Device Regulations* is available on the Justice Canada website:
http://www.laws.justice.gc.ca/en/f-27/sor-98-282/text.html

The STED format is based upon the goal for both regulators and manufacturers to strive for the least burdensome means to demonstrate conformity to the Essentail Principles for medical devices.

The documents generated by GHTF, Study Group 1 or the TPD for implementing this pilot program include the following:

- The TPD's Fact Sheet on GHTF and STED available on the TPD website at: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/ghtf_sted_fact_sheet_e.html
- The TPD draft Guidance document for this pilot program (this document)
- Appendix 1: A Notice to Industry announcing the proposed pilot premarket program
- Appendix 2: The GHTF Study Group I draft STED document
- Appendix 3: The GHTF document entitled *Essential Principles of Safety and Performance of Medical Devices*

3.0 Scope

As the GHTF wants to assess the international utility of the draft STED document, manufacturers are encouraged to prepare and submit STEDs for the *same device* to as many of the GHTF member countries as possible. The following countries are participating members of the GHTF: Canada, United States, Australia, Japan and the European Union. The GHTF also encourages manufacturers to try the STED format for different classes of devices that are candidates for the pilot program.

In order to achieve a more coordinated process, the device categories proposed in the scope and duration of the pilot program is consistent with the other member countries of GHTF.

Due to the current workload considerations, only applications for *new device licences* (not licence amendments) for the generic types of devices listed in Table 1 will be considered by the TPD for the pilot program.

The pilot program is anticipated to run for one year from the posted date of this guidance document.

Table 1: Candidate Devices for the Pilot Premarket Program

Intravascular Catheters
External Infusion Pumps
Endosseus Dental Implants
Hemodialyzers and Hemodialysis Catheters
Plasma Cells Separators for Therapeutic Use
X-Ray Bone Densitometers
Fluoroscopic X-ray
Urological Catheters
ECG Monitors
Computed Tomography Scanners
Magnetic Resonance Imaging Devices
PTCA Catheters
Coronary Stents
Implantable Pacemakers
Implantable Cardioverter Defibrillators
Orthopedic Implants

4.0 Procedures

A new device licence application for a Class III or a Class IV medical device will contain a premarket review document in addition to the general requirements of section 32(1). The premarket review document contains the evidence to support the requirements of Section 32(3) for Class III devices, or 32(4) for Class IV devices.

The Medical Devices Bureau will accept Class III and IV device licence applications in the draft STED format instead of the customary format for the candidate devices listed in Table 1 from those manufacturers who wish to participate in the pilot program.

A licence will be issued if, after reviewing the information included in the licence application, it is determined that the medical device conforms to the safety and effectiveness requirements.

Section 35(1) of the *Medical Devices Regulations*, provides a provision for ADDITIONAL INFORMATION or documentation from the manufacturer where the evidence submitted in support of the licence application requirements of Section 32 is insufficient to determine whether the device meets the safety and effectiveness requirements of Section 10 to 20.

The TPD targets to review Class III and IV device licence applications in the STED format within the performance standards outlined in the *Policy on the Management of Licence Applications and Investigational Testing Authorizations* posted on the TPD website at:
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/mdlappl-pol_final_e.html

There will be no expedited review of applications, unless the device merits such a process under current policies.

4.1 Administrative Instructions

Manufacturers who intend to submit a Class III and IV device licence application and are interested in participating in the pilot program should ensure that the candidate device is subject to premarket review by TPD and verify that the medical device is identified in Table 1.

The manufacturer must notify the person identified in Section 4 of this document of the intent to submit a Class III or IV device licence application using the draft STED format for the premarket submission. The person will inform the manufacturer whether or not TPD will accept and evaluate the application.

The manufacturer should submit the completed submission in the format described in the draft STED document. Included should be any additional required information described in Section 6.0 below, either in the cover letter as indicated or as additional sections of the submission using the draft STED format.

Please clearly identify on the cover page, in bold large print: **Global Harmonization Pilot Class III or Class IV Device Licence Application.**

Documents should be submitted to:

Therapeutic Products Directorate
Medical Devices Bureau
Room 1605, Main Statistics Canada Building
Tunney's Pasture, Locator: **0301H1**
Ottawa, Ontario
K1A 0L2

5.0 Presentation of the Review Document

Information in the document should be recorded in either English or French. Material in another language other than English or French must be accompanied by an English or French translation. Only one copy of a review document is required.

All documents should be legible, and the page size, including tables, should be uniform. The submission should be bound for easy access, for example in a three-ring binder. Each volume must be clearly labelled and numbered both on the spine and on the front cover.

The pagination may be sequential for the entire submission or by volume. In the executive summary and the table of contents, individual sections of text should be identified both by the assigned decimal number and by the correct title. Cross-references should include both volume and page numbers.

6.0 Class III and IV Device Licence Application

6.1 Elements of a Class III Review Document

A licence application for a Class III medical device must contain evidence in support of the requirements of Section 32(3) of the *Medical Devices Regulations*. These requirements are grouped into four general sections.

Device Licence Application Form
Executive Summary
Table of Contents
1 Background Information
1.1 Device Description
1.2 Design Philosophy
1.3 Marketing History
2 Summary of Safety and Effectiveness Studies
2.1 List of Standards
2.2 Method of Sterilization
2.3 Summary of Studies
2.4 Bibliography
3 Labelling
4 Quality System Requirements

Table 2 "Comparison of Section 32(3) of the *Medical Devices Regulations* to the draft STED Document" below provides a comparison of Class III device licence application requirements (applicable to the candidate devices in Table 1) to the *Essential Principles of Safety and Performance of Medical Devices* in the draft STED document.

Table 2: Comparison of Section 32(3) of the *Medical Devices Regulations* to the Draft STED Document

Requirements under *Medical Devices Regulations*		Corresponding STED Section
Section 32(3)(a)	**Description of the device**	Section 7.2.1
Section 32(3)(a)	**Description of the materials used in its manufacture**	Section 7.2.2
Section 32(3)(a)	**Description of the materials used in its packaging**	Section 7.2.2
Section 32(3)(b)	**Description of the features**	Section 7.2.1
Section 32(3)(c)	**"Marketing history"**	Appendix C.3
Section 32(3)(d)	**List of the standards**	Section 7.3.1
Section 32(3)(e)	in the case of a device to be sold in a sterile condition, a **description of the sterilization method used**	Section 7.2.3
Section 32(3)(f)	**Summary of safety and effectiveness studies and conclusions drawn**	Section 7.3.1 and 7.3.2
Section 32(3)(g)	a copy of the device **label**; Section 23 - language requirements	Section 7.4 Country specific requirement
Section 32(3)(h)	a **bibliography**	Section 7.3.2 and Appendix C.4
Section 32(3)(i)	a valid **quality system certificate**, in compliance with the appropriate quality system standard ISO 13488-1996 or ISO 13485-1996.	Effective May 14, 2003. Canada-specific requirement

Canadian requirements not cross referenced to a specific section of the STED document must be addressed in the covering letter or in a supplemental section of the submission. These elements include:

- Bilingual language requirements
- Quality system certificate

In addition, Section 7.5 and 7.6 of the draft STED document, which addresses risk analysis and

manufacturing information, is ordinarily not a requirement for a Class III device licence, however such information may be requested as additional information under Section 35 of the *Medical Devices Regulations*.

6.2 Elements of a Class IV Review Document

A licence application for a Class IV medical device must contain the information and documents described in Section 32(4)(a) to (p) of the *Medical Devices Regulations*. These requirements are grouped into eight general sections.

Device Licence Application Form
Executive Summary
Table of Contents

1 Background Information
- 1.1 Device Description
- 1.2 Design Philosophy
- 1.3 Marketing History

2 Risk Assessment
3 Quality Plan
4 Device Specific Detailed Information
- 4.1 Material Specifications
- 4.2 Manufacturing Process Specifications
  - 4.2.1 Method of Manufacture
  - 4.2.2 Quality Control Activities
- 4.3 List of Standards

5 Safety and Effectiveness Studies
- 5.1 Preclinical and Clinical Studies
- 5.2 Process Validation Studies
- 5.3 Software Validation Studies (if applicable)
- 5.4 Literature Studies

6 Devices Containing Biological Material (if applicable)
7 Device Label
8 Quality System Requirements

Table 3: Comparison of Section 32(4) of the *Medical Devices Regulations* to the Draft STED Document

Requirements under Regulations		Corresponding STED Section
Section 32(4)(a)	**Description of the device**	Section 7.2.1
Section 32(4)(a)	**Description of the materials used in its manufacture**	Section 7.2.2
Section 32(4)(a)	**Description of the materials used in its packaging;**	Section 7.2.2
Section 32(4)(b)	**Description of the features**	Section 7.2.1
Section 32(4)(c)	**"marketing history"**	Appendix C.3
Section 32(4)(a)	a **risk assessment**	Section 7.5
Section 32(4)(a)	**quality plan**	Canadian specific requirement
Section 32(4)(a)	the **specifications** of the materials	Section 7.2.2
Section 32(4)(a)	**manufacturing process**	Section 7.6 and 7.3.1
Section 32(4)(a)	**list of the standards**	Section 7.3.1
Section 32(4)(i)	**detailed** safety and effectiveness **studies**	Section 7.3.1 and Appendix C.4
Section 32(4)(l)	**summary and conclusions** of **studies** in Section 32(4)(i)	Section 7.3.1 and 7.3.2
Section 32(4)(n)	**bibliography**	Section 7.3.2 and Appendix C.4
Section 32(4)(o)	a copy of the device **label**;	Section 7.4
	Section 23 - language requirements	Canadian specific requirement
Section 32(4)(p)	a valid **quality system certificate**, in compliance with the appropriate quality system standard ISO 13488-1996 or ISO 13485-1996.	Effective May 14, 2003. Canada-specific requirement

Canadian requirements not cross referenced to a specific section of the STED document must be address in the covering letter or in a supplemental section of the submission. These elements include:

- Bilingual language labelling
- Quality plan
- Quality system certificate

7.0 Contact

If you are interested in participating, or have questions regarding this pilot program, please contact:

Nancy Shadeed
Head, Regulatory and Scientific Section
Licensing Services Division
Medical Devices Bureau
tel: (613) 954-0285
fax: (613) 957-6345
nancy_shadeed@hc-sc.gc.ca

Appendix 1: Notice to Industry

The Therapeutic Products Directorate (TPD) is announcing the start of a pilot premarket review program for medical devices on January 1, 2001 and is soliciting participation from the medical devices industry. The pilot program is to evaluate the utility of a document developed by the Global Harmonization Task Force (GHTF), Study Group 1 (SG1), entitled "*Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices* (STED)".

The pilot program is being undertaken in a number of participating countries represented on the GHTF. It is envisaged that the pilot program will run until December 2004, but this may vary depending on the level of participation by industry. At the conclusion of the study, SG1 will evaluate the findings from different regions.

Contact
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TEL: (613) 954-0285
FAX: (613) 957-6345

Appendix 2: Summary Technical Documentation for Demonstrating Conformity to the Essential Principle of Safety and Performance of Medical Devices (STED) - Draft

This document (SG1-N011R16) is available on the GHTF website under Study Group 1 \ Working Drafts at:
http://www.ghtf.org/

Appendix 3: *Essential Principles of Safety and Performance of Medical Devices*

This document (SG1-N020R5) is available on the GHTF website under Study Group 1 \ Final Documents at:
http://www.ghtf.org/