



GUIDANCE DOCUMENT

Recognition and Use of Standards under the *Medical Devices Regulations*

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Health Products and Food Branch

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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 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 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.

Document Change Log			
File name	md_gd_standards_im_ld_normes_e.wpd	Replaces	standards_normes_pol_e.pdf
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Change	Location (section, paragraph)	Nature of and/or Reason for Change
1	Full Document	Separate guidance document from the list of standards to facilitate the process of updating either document.
2	Full Document	Update template of policy to reflect the new Guidance Document template required.
3	Full Document	Editorial changes to improve clarity of the document.
4	Section 2.1.2, Final Paragraph	Emphasize that in some cases, data must still be provided with a Declaration of Conformity.
5	Section 2.1.1, Paragraph 2	Identify newly separated list of standards.
6	Section 2.1.1, Final Paragraph	Identify new location for Declaration of Conformity template.

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1 INTRODUCTION

1.1 Objective

To provide guidance for manufacturers on the use of standards in demonstrating compliance with the *Safety and Effectiveness Requirements* (section 10 to 20) and *Labelling Requirements* (section 21 - 23) of the *Canadian Medical Devices Regulations* (Regulations).

1.2 Scope and Application

This guidance will apply to applications for new and amended medical device licences, and applications for investigational testing, special access, and custom-made device authorizations.

1.3 Background

The Regulations specify *Safety and Effectiveness Requirements* (Sections 10 to 20) and *Labelling Requirements* (Section 21-23) which all medical devices must meet. Because these requirements are stated in general terms, both manufacturers and Health Canada will frequently need clearly defined criteria for determining whether a device meets these requirements.

One way to provide such criteria is to make use of standards issued by national or international standards writing organizations. Health Canada believes that conformance with recognized medical device standards, in whole or in part, can provide assurance of safety and effectiveness for those aspects of medical devices addressed by the standard. However, not all devices, or elements of device safety and effectiveness may be addressed by recognized standards, especially for new types of devices and emerging technologies.

The use of recognized standards can improve consistency in the interpretation of the Regulations. Specifically, if an application for a medical device licence or authorization contains a “Declaration of Conformity” to a recognized standard, this will in many cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standard. In some cases, conformance with recognized standards may not always be a sufficient basis for regulatory decisions.

In keeping with an established policy of Health Canada, efforts will be made to harmonize Canada’s requirements with those of other countries, by using international standards wherever possible. This will benefit industry by reducing regulatory obstacles and allowing safe, effective, quality products to enter international markets more quickly.

2 GUIDANCE FOR IMPLEMENTATION

2.1 Procedures for Use of Recognized Standards

2.1.1 General

Health Canada will, from time to time, publish an updated list of recognized standards. There may be cases in which certain parts of a recognized standard are not required under the Regulations, or are not consistent with the Canadian Regulations or other Canadian legislation. In such cases, Health Canada will limit the extent of its recognition to certain parts of the standard.

The current list of Health Canada recognized standards is posted on the Health Canada website and can be found at the following address:

http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst_2_e.html

Conformance with recognized standards is voluntary for manufacturers. A manufacturer may choose to demonstrate conformance with a recognized standard or may elect to address the relevant issues in another manner.

If a standard is recognized, a manufacturer applying for a licence for a device to which that standard applies must either:

- (a) meet the standard; or
- (b) meet an equivalent or better standard; or
- (c) provide alternate evidence of safety or efficacy

In case the manufacturer chooses option (b) or (c), detailed information must be submitted with the device licence application. If the manufacturer does none of the above, a licence will not be issued.

If a manufacturer elects to demonstrate conformance with the safety and effectiveness requirements or the labelling requirements by using one or more recognized standards, a “Declaration of Conformity” must be submitted in accordance with Section 2.1.2.

The form for making a “Declaration of Conformity” is posted on the Health Canada website and can be found at the following address:

http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index_e.html

2.1.2 Licensing and Authorization

A manufacturer may demonstrate conformance to a recognized standard in partial fulfilment of the applicable safety and effectiveness requirements by means of a “Declaration of Conformity” in order to obtain:

- (a) a medical device licence for a Class II, III, or IV device (Section 32 of the Regulations) and if applicable, a medical device licence amendment;
- (b) an authorization for special access (Section 71(2) of the Regulations);
- (c) an authorization to sell or import a Class III or IV custom-made device (Section 71(2) of the Regulations);
- (d) an authorization for investigational testing of a Class II, III, or IV device (Section 82 of the Regulations).

All records, including the actual test data or information relating to a manufacturer’s compliance or “Declaration of Conformity” with standards, should be maintained for a period of two years after a licence or authorization has been obtained for the device, or for the expected design life of the device, whichever is longer.

If Health Canada ceases to recognize a standard (for example, because it has been superseded by a later edition) conformance with it will no longer be acceptable for obtaining a new device licence or an authorization. However, licences and authorizations issued under conformance with the old standard will continue to be valid.

The “Declaration of Conformity” must:

- (a) identify the recognized standard or standards that were met including the edition of the standard;
- (b) attest that all the requirements for each standard have been met, except for requirements which do not apply or deviations as noted below;
 - (i) identify any sections or requirements of a standard that are not applicable to the device;

- (ii) identify any ways in which a standard has been adapted for application to the device in question, for example, by choosing one of several acceptable test methods specified in the standard;
- (iii) specify any deviations from a standard, such as deviations from an international standard necessary to meet national or provincial regulations;
- (c) specify any differences between the device tested for conformance with a standard and the device to be marketed, and justify the use of the test results in case of differences;
- (d) provide the name and address of any third-part laboratory or certification body that was employed in determining conformance with a standard.

Where a recognized standard describes a test method, but does not specify a unique pass and/or fail criterion, the supporting evidence must be submitted.

2.2 Information Beyond the Scope of Recognized Standards

It must be recognized that the review of a specific device may raise issues not addressed by recognized standards. For example, a Class III or IV medical device may require data from clinical testing not addressed in recognized standards.

Manufacturers must ensure that applications contain all the information necessary to support a determination of safety and effectiveness including evidence beyond the extent of recognition of a standard.