Guidance on using standards to support compliance with the Medical Devices Regulations

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Ligne directrice sur l'utilisation des normes en vue d'assurer le respect du Règlement sur les instruments médicaux

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

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Introduction

This document provides guidance to manufacturers on using standards to support compliance with the following requirements under the Medical Devices Regulations (regulations):

- safety and effectiveness requirements
- labelling requirements

Scope and application

Standards may be used to demonstrate compliance for all classes of medical devices.

However, this guidance focuses mainly on using standards for applying for:

- new and amended medical device licences or authorizations
- investigational testing, special access and custom-made device authorizations

Background

The regulations specify that all medical devices must meet the requirements for:

- safety and effectiveness (sections 10 to 20)
- labelling (sections 21 to 23)

Because these requirements are stated in general terms, clearly defined criteria are helpful for determining whether a device meets these requirements.

By providing such criteria, recognized national or international standards offer assurance that aspects of the medical devices addressed by a standard are safe and effective. However, not all devices or elements of safety and effectiveness are addressed by recognized standards (for example, new types of devices and emerging technologies).

The use of recognized standards can help ensure that the regulations are interpreted consistently. For example, an application for a medical device licence or authorization that declares conformity to a recognized standard in the Declaration of Conformity Form often eliminates the need to review the test data for those aspects of the device addressed by the standard. Note: In some cases, conformance with recognized standards may not always be a sufficient basis for regulatory decisions.

Health Canada has long collaborated with international partners to ensure that our regulatory practices and standards are consistent, whenever possible, with international norms. Consistency helps to reduce regulatory obstacles and allows safe, effective, quality products to enter multiple markets more quickly.

Learn more about our international collaboration.

Regulatory context

Health Canada issues a medical device licence or authorization for Class II, III or IV devices when there's acceptable evidence showing the device meets the regulatory requirements.

Learn more about:

- supporting evidence to be provided
- supporting clinical evidence to be provided

The List of Recognized Standards for Medical Devices is provided to help manufacturers comply with the *Medical Devices Regulations* only. Manufacturers may also need to follow other standards to comply with other federal, provincial and territorial or municipal regulations, acts and certifications that apply to their medical devices. These can include, for example:

- the Radiation Emitting Devices Act
- provincial and territorial electrical regulations
- Innovation, Science and Economic Development Canada certifications and registrations

These regulations, acts and certifications are separate and distinct from the *Medical Devices Regulations*. They are not addressed by the licensing or authorization process required by these regulations. Therefore, in addition to having a medical device licence or authorization, medical devices must also have all other relevant authorizations and certifications that are required by other authorities.

Contact the applicable authorities for information on these requirements.

Guidance for implementation

The following provides manufacturers with information to help them use standards appropriately to support compliance with the *Medical Devices Regulations*.

Procedures for using recognized standards

Health Canada recognizes certain standards as supporting an aspect of safety or effectiveness appropriately. These standards are listed in the List of Recognized Standards for Medical Devices.

General

Health Canada updates the list of recognized standards from time to time:

- List of recognized standards for medical devices

There may be cases when certain parts of a recognized standard are not required under the regulations or are not consistent with the regulations or other Canadian legislation. In such cases, we will limit the extent of its recognition to certain parts of the standard.

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

If a standard is recognized, a manufacturer applying for a licence or authorization 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 effectiveness

A manufacturer that chooses b) or c) must submit detailed information with the application demonstrating equivalent evidence of safety or effectiveness compared to the recognized standard. For example, if the manufacturer uses an older, unrecognized version of a recognized standard, the manufacturer must:

- provide a detailed comparison between the unrecognized and current recognized version
- justify the use of the unrecognized standard

If the manufacturer fails to provide this, we may not license or authorize the device.

If a manufacturer uses 1 or more recognized standards to demonstrate conformance with the safety and effectiveness or labelling requirements, they must submit a Declaration of Conformity. Refer to the following section for details.

Declaration of Conformity Form

Licensing and authorization

Manufacturers may demonstrate their conformance to a recognized standard in partial fulfilment of the applicable safety and effectiveness requirements under the regulations through a Declaration of Conformity to obtain:

a) a medical device licence for a Class II, III or IV device (section 32) and, if applicable, a medical device licence amendment
b) an authorization for special access (subsection 71(2))
c) an authorization to sell or import a Class III or IV custom-made device (subsection 71(2))
d) an authorization for investigational testing of a Class II, III or IV device (section 82)
e) an authorization for a device for urgent public health need (part 1.1)

Manufacturers should maintain all records for 2 years after obtaining a licence or authorization for the device, or for the expected life of the device, whichever is longer. Records include the actual test data or information relating to a manufacturer's compliance or declaration of conformity with the standards.

When Health Canada ceases to recognize a specific standard, simple conformance with this standard is no longer acceptable for obtaining a new device licence, licence amendment or authorization. This can happen, for example, when the standard has been superseded by a later edition and the transition period has ended, or the standard is no longer considered acceptable. However, licences and authorizations issued under the old standard are still valid.

Manufacturers should follow the instructions in the General section for conforming to standards in this case.

The Declaration of Conformity must:

- identify the recognized standard or standards that were met, including the edition of the standard
- attest that all the requirements for each standard have been met, except for requirements that do not apply or for any of the following deviations:

    - identify any sections or requirements of a standard that do not apply to the device
    - identify any ways in which a standard has been adapted for the device (for example, by choosing 1 of several acceptable test methods specified in the standard)
    - specify any deviations from a standard, such as deviations from an international standard necessary to meet national or provincial regulations
- 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 if there are differences
- provide the name and address of any third-party laboratory or certification body used to determine conformance with a standard

Submit supporting evidence where a recognized standard describes a test method, but does not specify a unique pass and/or fail criterion.

Information beyond the scope of recognized standards

The review of a specific device may raise issues that recognized standards do not address. For example, a Class III or IV medical device may require data from clinical testing or other non-clinical testing not addressed in these standards.

Manufacturers must ensure that applications contain all the information necessary to support a determination of safety and effectiveness. This information may include evidence not specifically covered in the recognized standards.

Version recognition for medical device-related standards

Health Canada uses the name of the organization that developed the standard and the standard's designation number to list recognized standards. Some standards may also list an edition and year.

We recognize the latest version of a standard that does not list an edition and year. However, when a new version of one of these standards is published, we recognize the most recent version **and** the previous version, including any amendments or corrigenda, for 3 years.

The 3-year transition period begins on the date that the organization published the latest version. Any transition period that is specified in the latest version of the standard supersedes the 3-year transition period, unless otherwise stated in the list of recognized standards.

When we list a standard with an edition or year, we recognize only that specific version of the standard. We do not recognize newer versions if the edition or year listed is not the latest version.

We recognize only the latest version, without a transition period, if the edition or year of the latest version is listed.

An edition or year would be listed when, for example:

- changes have been made to a recognized standard and the new version does not adequately support compliance with our safety and effectiveness requirements
- the latest version contains critical new information and conformance to the previous version is no longer adequate to support compliance with our safety and effectiveness requirements

A note may be added to any standard on the list to address such things as unrecognized clauses and clarifications. The note may include the specific year or edition to which the note relates. This avoids any confusion with other versions of the standard, in case clauses are rearranged or renumbered between versions. For example:

- Except: Section 7.1.3 (as labelled in 2009, Ed. 1) or
- Devices subject to Clause 5.3.2 may require additional testing beyond that which is specified in Clause 5.3.2 (2018, Ed. 5)

Note: Manufacturers must still specify the year or edition of standards used in their applications and on their Declaration of Conformity Forms. The date when we receive an application will be used for the purpose of recognizing an edition. If a transition period ends after an application is submitted, the application will not have to conform to the newer standard version.

Note about guidance documents in general

Guidance documents provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. They also provide assistance to staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They 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 always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents.