Health Canada Recognition and Use of Standards

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Cindy Evans
Medical Devices Bureau
Health Canada



Canada

Overview of Presentation

- How standards are used in support of meeting requirements of the Canadian Medical Devices Regulations
- HC process to update and implement list of recongnized standards
- Challenges and Opportunities




Role of Standards in the Application of the Regulations

- Requirements for device safety, effectiveness and labelling are stated in general terms in Canadian *Medical Devices Regulations (Regulations)*
- Clearly defined criteria are often needed to determine whether a specific device meets these requirements
- National and international consensus standards can provide such criteria
- Use of these standards can increase consistency in the interpretation of the requirements of the *Regulations*




Standards-Based Approach to Licensing

- MDB recognizes consensus standards for use in pre-market review of devices
- Conformity with these standards, in whole or in part, provides assurance that the device meets the safety, effectiveness and labelling requirements addressed by the standard
- The Therapeutic Products Directorate's guidance document on *Recognition and Use of Standards* formalizes this practice




Types of Medical Device Standards

Test Methods

- e.g., biocompatibility, mechanical testing

Material Specifications

- e.g., 316L Stainless Steel, titanium alloys

Performance

- e.g., safety of medical electrical equipment

Labelling

- e.g., permanent marking of orthopaedic implants

Device Specific

- e.g., catheters, pacemakers




Guidance Document

Recognition and Use of Standards under the Medical Devices Regulations (2006-09-22)

Posted at: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_standards_im_ld_normes-eng.php

List of Recognized Standards (Draft 2014-05-15)

Posted at: http://www.hc-sc.gc.ca/dhp-mps/consultation/md-im/consult_md_stand_im_draft_ebauche_norm_prop_lst-eng.php




Legal Status of Guidance Document

- Use of TPD-recognized standards is voluntary, not mandatory
- Manufacturers may choose instead to:
  - demonstrate conformity with an equivalent or better standard; or
  - provide alternate evidence of safety and effectiveness
- licence will not be issued if none of the above are done




Licensing Requirements

- Manufacturers must list the standards met (Section 32 of the *Regulations*)
- Standards cited must be acceptable to Medical Devices Bureau (MDB) to serve as evidence of safety and effectiveness
- *Regulations* require mandatory compliance with ISO 13485 for Quality Systems




Impact to Review Process

- If a medical device conforms with a recognized standard with unambiguous pass and fail criteria, and no options for testing to be performed;
  - TPD will consider it to have met the safety, effectiveness and/or labelling requirements addressed by the standard
- TPD will accept a manufacturer's declaration of conformity with the standard, but a false declaration could result in loss of the licence
- Manufacturer will still need to submit further evidence in support of safety and effectiveness requirements not covered by the extent of the standard




Use of Recognized Standards – Test Method

- If a medical device conforms with a recognized standard that provides only a test method without pass and fail criteria, or if there are several testing options allowed by the standard (which is common):
  - TPD will require data to be submitted so that the full extent of the testing and the results can be understood.
- Data to be submitted could include a description of testing done, a description of the pass and fail criteria used (with justification), or a full test report (especially for Class IV).




Declaration of Conformity

- Identify recognized standard met (including edition or version)
- Attest all requirements have been met, or identify requirements not applicable, or any deviations from the standard
- Specify any differences between the device tested and the device to be marketed, and justify the use of the test results in case of differences
- Provide name and address of third-party laboratory or certification body employed to determine conformance




Additional Information

- Pre-market review of a specific device may raise issues not addressed by recognized standards; e.g., a Class III or IV medical device may require data from animal testing or clinical testing not addressed in recognized standards
- Manufacturers must ensure that the application contains all the information necessary to support a determination of safety and effectiveness, including safety and effectiveness evidence beyond the extent of recognition of a standard.




HC Approach:
Selecting Standards for Recognition

- Any consensus standard consistent with the *Regulations* is eligible
- Only current editions of final published standards will be recognized
- Emphasis given to international standards to harmonize with other countries, but other standards may also be used if appropriate
- MDB evaluates standards for suitability
- Manufacturers and the public may propose standards for recognition




Criteria for Recognition

- The standard sets minimum safety or effectiveness requirements
- The standard sets labelling requirements
- The standard specifies an acceptable test method
- Preference is for horizontal standards and those that further global harmonization




Updating the List

- List of recognized standards is periodically updated and posted on Health Canada website
- New editions are recognized after public comment period (effective transition period)
- Obsolete editions of standards are deleted
- Standards may be withdrawn if they no longer meet TPD’s regulatory needs




Challenges and Opportunities

- Engagement of regulators in the standards development process
- Implications when standard lacks clear pass/fail criteria
- International versus Canadian Standards
- Clinical Data standards