



AdvaMed works with industry and governments around the world to minimize regulatory-related barriers between patients and life-saving and life-improving medical technologies.

Central to this work is global medical device regulatory convergence. Regulatory convergence is the process of aligning the technical regulations, standards, and conformity assessment criteria for medical devices in all countries toward a single set of internationally harmonized criteria.

The World Health Organization urges public health authorities around the world to economize their limited public health resources by relying on international standards as a basis for national regulations and by relying on the conformity assessment results of other jurisdictions. The government funds required to develop a regulation in isolation, to test a product that has already been tested, or to certify a product that has already been certified are funds that a health agency can use to strengthen post-market surveillance, to digitize import review procedures, to accelerate good manufacturing practice inspections, to modernize IT infrastructure, or to upgrade regulatory inventory. More broadly, such economized public health resources can be used to improve healthcare delivery by hiring and training physicians, nurses, and procurement staff; by investing in hospitals, clinics, and other points of care; by upgrading health IT systems, and to otherwise improving patient treatment and care delivery.

This document summarizes the primary international reference documents for medical device regulators regarding regulatory convergence and the use of international standards.

International Health Guidance

1. [World Health Organization - Global Model Regulatory Framework for Medical Devices Including IVD Medical Devices](#) (all), including:

- Stepwise Approach (Section 4 - page 21)
 - Reliance and Recognition (Section 4.1.1 – page 21)
- 4.2 Basic-level controls and their enforcement (page 23)
 - 4.2.1.2 – “...*The preferred, but optional, way by which the manufacturer may demonstrate conformity with the Essential Principles is to apply voluntary international standards that are appropriate and relevant. The law should include provisions allowing the regulatory authority to formally recognize such standards for that purpose (see section 4.3.1.3).*...”
- 4.3.1.3 – “...*At the expanded level, the regulatory authority may wish to establish a procedure to identify national versions of international standards that it accepts as providing presumption of compliance to specific Essential Principles, i.e. “recognized standards”. Preference for recognition should be given to international standards, e.g. those of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), regional standards and the national versions of international standards. It is also important that national standards correspond to the current version of international standards. As international standards are periodically revised, national standards will have to be revised accordingly and the authority should establish a transition period for manufacturers to adopt the new versions. To maintain the necessary flexibility in utilizing standards, it is better to adopt*...”



a system of recognizing standards through guidance documents or guidelines than placing the standards into legislation; they can then be updated to stay current and can be revised much faster than legislation can be updated.”

2. [International Medical Device Regulators Forum \(IMDRF\) documents](#) (all), including:

- **2a. [IMDRF N47 - “Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices”](#)**
 - Annex A: Use of Standards in Meeting Essential Principles
 - B. Use of Standards by Regulatory Authorities having Jurisdiction
 - *“These standards should, wherever possible, be standards incorporating the thinking of the global marketplace and help support the development of consistent expectations between Regulatory Authorities having jurisdiction. In the absence of international consensus standards, it may be appropriate for Regulatory Authorities having jurisdiction to accept the use of regional or national consensus standards or industry standards.”*
- **2b. [IMDRF N51 - “Optimizing Standards for Regulatory Use”](#)**
 - B. Use of Standards by Regulatory Authorities having Jurisdiction
 - 1.2 Role of standards in regulatory processes
 - *Although regulatory processes among IMDRF regions differ, RAs [regulatory authorities] share the common objectives to ensure medical device safety and performance and to protect public health. International consensus standards are based upon science, technology and experience and generally reflect the best experience of industry, researchers, consumers, regulators and other experts worldwide. IMDRF members affirm their collective belief that reliance upon consensus standards is a key element of a robust regulatory framework. Appropriate use of standards will promote efficiencies and innovation while facilitating objective assessment of device safety and performance.”*

International Trade Obligation

3. [World Trade Organization – Agreement on Technical Barriers to Trade](#)

- Article 2.4 – *“Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations...”*



ISO Guidance on use of International Standards

4. ISO Guide 21-1 “Regional or national adoption of International Standards and other International Deliverables — Part 1: Adoption of International Standards”

“0.2 International Standards are widely adopted at the regional or national level and applied by manufacturers, trade organizations, purchasers, consumers, testing laboratories, authorities and other interested parties. Since these standards generally reflect the best experience of industry, researchers, consumers and regulators worldwide, and cover common needs in a variety of countries, they constitute one of the important bases for the removal of technical barriers to trade. This has been explicitly acknowledged in the Agreement on Technical Barriers to Trade of the World Trade Organization (WTO TBT Agreement).

It is important that every effort be made to adopt and use International Standards as regional or national standards and, consequently, to withdraw conflicting regional or national standards as soon as practicable for the reasons mentioned above. Only by developing a global approach can the benefits of standardization be fully realized. However, full adoption may not be practicable in all cases for reasons such as regional or national security, protection of human health or safety, or protection of the environment, or because of fundamental climatic, geographical or technological problems. The WTO TBT Agreement recognizes that these are legitimate reasons for regional or national deviations.

0.3 The adoption of an International Standard as a regional or national standard will be extremely difficult if the regional or national rules or traditions concerning structure and layout of regional or national standards differ from those of the standard being adopted. It is therefore recommended to apply, as far as possible, the ISO/IEC Directives, Part 2, for the preparation of regional and national standards.

Even for the cases referred to in 0.2, every effort should be made to reduce the deviations to a rational minimum. Moreover, where deviations from International Standards exist, it is important to identify the deviations clearly and to state the reasons for the deviations. If International Standards are adopted only by means of a re-edited version, it is extremely difficult to identify the technical deviations owing to the presentation differences (that is differences in the structure and wording) of the original standard. On the other hand, a clearly identified deviation will have a tendency to disappear because as long as it remains visible, the question as to whether it is still necessary will arise repeatedly, while a hidden deviation may not disappear even when no longer justified.

0.4 It is recommended that as much information as possible be given about the correspondence of regional or national standards that adopt International Standards (or are based on them). This information should be displayed in a prominent place on the regional or national standard (preferably on the title page and in the foreword), in standards lists, catalogues, year-books and any other media for retrieval purposes. When quoting an International Standard, at least its number and date of publication should be given. If a regional or national standard does not exist materially (for example, if the International Standard has been adopted by the endorsement method), this information about correspondence should be given in standards listing media as mentioned above.”



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See Also

- [Using ISO and IEC standards to support public policy](#)
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