

Position Statement

Consensus Standards for Medical Devices¹

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Introduction

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purpose.¹ Standards may establish a wide range of criteria related to medical and surgical devices. These criteria may include guides, material specifications, or performance testing. Most medical devices use consensus-based standards such as those produced by American Society for Testing and Materials (ASTM) and International Organization for Standardization (ISO). Consensus standards are developed by private-sector standards bodies using a voting and resolution process which is open to public scrutiny.²

Standards and the Regulatory Process

The value of clinically relevant consensus standards is paramount to the American Academy of Orthopaedic Surgeons (AAOS). Orthopaedic surgeons expect that the devices they use, such as scalpels, artificial joint replacement systems, or ronguers, meet minimum standards for quality and functionality. Standards benefit surgeons by ensuring the quality of products they implant as well as assisting in communication efforts (surgeon to surgeon, surgeon to patient, and surgeon to manufacturer). The consensus process allows for the participation of orthopaedic surgeons, researchers, and regulatory personnel whose primary interest is in the development of safe and reliable standards for orthopaedic devices. Orthopaedic patients, in turn, benefit from the multi-party participation and transparent consensus process used in the development of medical device standards.

Standards forums in themselves provide one of the single most effective environments for surgeons to vocalize their needs and concerns directly to manufacturers and users simultaneously. Standards organizations are ideal conduits for the communication of surgeons' clinical needs, facilitating the subsequent transfer of technologies to the marketplace in the form of safer, more effective, and innovative products.

Standards and the Regulatory Process

Government regulators often give voluntary standards the force of law by citing them in laws, regulations, and codes. In the United States, the relationship between private-sector standards

organizations and the public sector has been strengthened with the 1995 passage of the National Technology Transfer and Advancement Act (Public Law 104-113).³ In 1997, Congress authorized the U.S. Food and Drug Administration (FDA) to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.⁴

Congressional recognition of consensus standards promotes governmental efficiency by allowing the adoption of private sector standards rather than relying on governmental development and maintenance of pertinent standards. When government agencies use privately developed standards, savings are achieved by reducing formerly duplicative standards development efforts. Governmental regulatory bodies in many countries similarly recognize consensus standards as efficiency in the regulatory submission process, allowing the regulatory body to accept evidence of manufacturer conformity with a recognized consensus standard in lieu of submitting additional evidence to demonstrate the safety or efficacy of the medical or surgical device.

Global Harmonization of Medical Device Standards

Domestic manufacturers of medical devices expand their territories into foreign markets, just as foreign medical device manufacturers export their products into the United States. With innovation and rapid advances in technology, annual medical device sales continue to grow at a rate of 6-10% in the United States.^{5,6}

Most medical devices are used globally. Their safety, performance, and consistent quality are therefore an international public health interest.⁷ In 2003, the World Health Organization (WHO) released a report entitled *Medical Device Regulation: Global Overview and Guiding Principles*, noting that “many countries lack access to high-quality [medical] devices and equipment...[it] is particularly rare in developing countries, where health technology assessments are rare and where little regulatory controls exist to prevent the importation or use of substandard devices.”⁸

The International Medical Device Regulators Forum, formerly the Global Harmonization Task Force, was founded in October 2011, when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization (WHO) convened to build upon the foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.¹⁰ The WHO has noted that without harmonization of regulatory systems, the proliferation of different national regulations can increase costs, hinder access to healthcare technologies, and even unwittingly jeopardize the safety of the patient.¹¹

The GHTF has established common guidelines entitled “Essential Principles of Safety and Performance of Medical Devices,” which, in the interests of public health, should be considered within the medical device regulatory oversight programs of all nations. The Essential Principles address issues of device safety, intended use, design, construction, packaging, and clinical evaluation.¹²

Standards and the Practice of Orthopaedic Surgery

Standards that are related to material and surgical devices can have a wide range of criteria and are published annually using the following general categories:¹³

- Classification – a systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use
- Guide – a series of options or instructions that do not recommend a specific course of action
- Practice – a definitive procedure for performing one or more specific operations or functions that does not produce a test result
- Specification – a precise statement of a set of requirements to be satisfied by a material, product, system, or service that indicates the procedures for determining whether each of the requirements is satisfied. Examples of such requirements are the test methods which need to be performed, and the performance levels which should be achieved with the test methods.
- Performance – criteria to ensure a device meets a prescribed test and delivers its intended function, such as strength, rotational, or durability requirements
- Terminology – a document comprising definitions of terms; description of terms; explanations of symbols, abbreviations, or acronyms
- Test method – a definitive procedure for the identification, measurement, and evaluation of one or more qualities, characteristics, or properties of a material, product, system, or service that produces a test result

The Role of the American Academy of Orthopaedic Surgeons (AAOS) in Standards Development

The AAOS holds patient safety in the highest regard, and acknowledges the importance of consensus standards which embody the highest concern for safety. The AAOS supports the participation of orthopaedic surgeons in national and international standards development organizations. These standards development organizations seek to promote public health and safety, and the overall quality of life; contribute to the reliability of materials, products, systems and services; both nationally and internationally.¹⁴ The AAOS believes that these goals ultimately serve the best interests of our patients and our profession.

The AAOS firmly believes that clinical orthopaedic contributions to the development of standards for orthopaedic devices will ensure the protection of our patients' vital interests in the consensus development of these standards. Orthopaedic surgeons participating in the development of medical and surgical device standards must consider patient safety above any other factor considered in the consensus process.

The AAOS recognizes that as technology and medical knowledge advance, standards must evolve. Orthopaedic surgeons and researchers must provide assistance in the development of appropriate standards for emerging orthopaedic biological products. The AAOS supports the continual, ongoing involvement of orthopaedic surgeons in monitoring national and international standards important to the practice of orthopaedics for clinical relevance, revising them as peer reviewed evidence from clinical, scientific and technological information warrant.

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