## Update on ANSI, ADA, AAMI, and ISO Standards Published: November 16th, 2023

National and international standards have long played an important role in shaping the design and quality of dental products and serving as guiding principles for practitioners to ensure the compatibility, safety, and effectiveness of the products they use with patients. We spoke with Dr. Shannon E. Mills, an independent health care consultant and lecturer based in Concord, New Hampshire, to learn more about the historical development of these standards, their significance in dental practice, and their broader impact on global markets and regulatory compliance. His active involvement in developing industry standards — as a member of the American Dental Association Standards Committees on Dental Products (ADA SCDP) and Dental Informatics (ADA SCDI) and the U.S. Technical Advisory Group to the ISO/Technical Committee 106 Dentistry — offers a unique perspective for us to learn from.

## How do standards influence the design of products we use and consume?

For almost all types of manufactured products encountered in daily life — from baling wire to furniture, electrical plugs, motor oil, and the most sophisticated electronics — national and international voluntary consensus standards establish uniform engineering or technical criteria, methods, and practices within an industry or profession.1,2

National, regional, and international standards provide guidance for manufacturers to ensure the compatibility, interoperability, safety, repeatability, and quality of products. Some standards also guide end users in the safe and effective use of standardized products. 1, 2

The design and composition of almost every device and material used in dental practice are influenced by national and international standards. Among the more notable examples are the handpiece couplers that allow dentists to use different brands and models of air-driven dental handpieces. Prior to the development of these standards, the couplers used to attach handpieces were proprietary.

Likewise, the nomenclature, size, shape, and materials used in the manufacturing of burs and diamonds have become standardized so that products from different manufacturers, made in different parts of the world, can be expected to be compatible with handpieces and perform safely and effectively if manufactured in conformance with ISO or ANSI standards.

### Who develops standards at the national and international levels? Around the world, industry standards are developed by standards development organizations (SDOs) that are

accredited by a national standards body. The American National Standards Institute (ANSI) is the national SDO for the United States.<sup>2</sup> ANSI supports the development, harmonization, and U.S. adoption of international standards through participation as a member body of international standards bodies, including the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).3

ANSI accredits and sets rules in the United States for myriad industry sectors, including dentistry. The American Dental Association (ADA) is the ANSI-accredited SDO for dental products. This work is accomplished by individuals and representatives of companies; government agencies; industry, labor, and trade associations; consumer groups; academics; and others with an interest in standards. ANSI also accredits U.S. Technical Advisory Groups (TAGs) that represent U.S. SDOs in international standards development activities. ANSI also accredits other SDOs that publish standards relevant to dentistry.

Examples include the Association for the Advancement of Medical Instrumentation (AAMI), which develops standards for sterilizers, instrument washers, and sterilization monitoring devices, and the International Safety Equipment Organization (ISEA), which develops standards for safety equipment, including protective eyewear and eyewash stations.

# How did the ADA become the accredited SDO for dental products?

The ADA has deep roots in standards development in health care. When the United States entered World War I in 1917, the Army needed to order large quantities of dental amalgam to deal with untreated tooth decay among recruits. Much of the amalgam available at that time was of inconsistent formulation and quality. In 1919, the Army asked the National Bureau of Standards (NBS) to develop a bid request to procure amalgam of standard formulation and clinical performance. In 1920, Dr. Wilmer Souder and an NBS colleague published their findings and created the first science-based specification for a dental material. These specifications served as the basis of the first international dental specification of the Fédération Dentaire Internationale (FDI World Dental Federation) and the International Standards Association (now ISO).4

the NBS developed became ADA Specification No. 1.4 This standard — many times revised — remains an American national standard today. All standards the ADA develops or adopts today are developed in accordance with the ADA Standards Scope

In 1928, the ADA took over as the national standards developer for the United States, and the amalgam standard

"Standardization in oral health care including terms and definitions; performance, safety, and specification

requirements of dental products; and clinically relevant laboratory test methods, all of which contribute to improved global health."5 ANSI-accredited ADA standards committees now develop standards that are recognized and used by

manufacturers, regulators, researchers, and clinicians both in the United States and around the world. How does ANSI interact with the ISO to develop international standards?

## The ISO is an independent, nongovernmental international organization located in Geneva, Switzerland, with a

membership of 165 national standards bodies that brings together experts to share knowledge and develop voluntary, consensus-based international standards that support innovation and provide solutions to global challenges. The ISO was founded with the idea of answering a fundamental question: "What's the best way of doing this?" Over the last 50 years, the ISO has developed standards for everything from shoes and shipping containers to toothbrushes and Wi-Fi networks. ISO standards help make the world a safer place and give consumers the

confidence that products are safe, reliable, and of good quality. Regulators and governments in many countries rely on ISO standards to help develop better regulation, thanks to the involvement of global experts. U.S. manufacturers gain access to world markets through conformance

with ISO standards. ISO standards development is performed by 240 technical committees (TCs) that develop standards for various industries. ISO TC 106 – Dentistry is the TC for dental products. The ADA's U.S. TAG to ISO TC 106 – Dentistry is

accredited by ANSI to represent the interests of America's dental manufacturing sector, dental professionals, and the public in developing international standards. How does the voluntary consensus process work? ANSI rules require standards developers to strive for balance among three categories: producers (manufacturers

and retailers), consumers (purchasers and end users), and general interest (academicians, scientists, and

## proposal may be for a new standard, a revision of an existing standard, or the adoption of ISO standards with or

standards.

without modification. Once the work item is approved, it goes through a series of drafts and ballots, culminating in circulation for an "All Interested Party Review" by members of the ADA Standards Oversight Committee. Then, a standard may be submitted to ANSI to be designated as an American National Standard. Not all ADA Standards Committee on Dental Products (SCDP)/SCDI work products (including white papers and technical reports) become ANSI

engineers). A standard is developed using a rules-based process that begins with a new work item proposal. The

The ADA, SCDP, and SCDI may also adopt standards or develop joint standards in collaboration with other U.S. SDOs, particularly in the areas of infection prevention, sterilization, and informatics. Examples include ADA adoption of AAMI standards for steam and dry-heat sterilizers and the current ongoing joint working group on steam sterilization in dental facilities. Manufacturers and distributors benefit from standards that help create a level playing field in domestic and

international markets. Standards allow manufacturers to produce products that meet established requirements

for composition, conformation, and performance. When a dentist goes online to order a forceps, a bur, a

handpiece, restorative materials, or personal protective equipment, they can be assured that the product conforms with ANSI or ISO standards and will be safe and effective. These standards also assure that products that require interoperability (e.g., handpieces, burs, diamonds, curing lights, electronic dental records) will work together irrespective of the manufacturer or country of origin. Conformance with standards should not stifle innovation or set a lowest common denominator for products, because manufacturers are free to exceed the requirements in response to the demands of consumers or to gain market advantage. Standards may set a floor in terms of product quality and safety, but from there, the sky's the

Hierarchy of International Standards Development Organizations for Dentistry CENELEC

International Standards Organizations

**Organizational Structure of National and International Standards Bodies** 



American National Standards Institute. 2022 [cited December 29, 2022]; Available from: https://www.ansi.org/. International Electrotechnical Commission (IEC). 2022 [cited December 29, 2022]; Available from: https://www.iec.ch/homepage. 4. Paffenbarger, G.C., J.A. Tesk, and W.E. Brown, Dental research at the National Bureau of Standards: how it changed the

**Author** Dr. Shannon E. Mills is an independent healthcare consultant and lecturer based in Concord, New Hampshire. A 1977 graduate of Baylor College of Dentistry, Dr. Mills served as Air Force Dental

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Science at Northeast Delta Dental and as vice president for strategy and business development for Northeast Delta Dental's subsidiary PreViser Corporation until his retirement in 2018. has authored and co-authored numerous scientific papers in peer-reviewed journals. While

Officer after graduation until he retired in 2005 to join the faculty of the University of Nevada School of Medicine. From 2007 to 2018 he was vice president for Professional Relations and

Dr. Mills is internationally recognized as an expert in dental infection prevention and safety, and serving on the Air Force Surgeon General's staff, he participated as an advisory group member for the CDC's "Guidelines for infection control in dental health care settings - 2003." Dr. Mills was the editor of the "Dental Unit Water Quality: Organization for Safety, Asepsis and Prevention (OSAP) White Paper and Recommendations — 2018." He's also actively involved in developing dental industry standards as a member of the American Dental Association Standards Committees on Dental Products (ADA SCDP) and Dental Informatics (ADA SCDI) and the U.S. Technical Advisory Group to the ISO/Technical Committee 106 Dentistry. Dr. Mills is the recipient of numerous awards for his service, including the OSAP James J. Crawford Award for Lifetime Achievement.



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