

1  **National and International Standards Workshop**

2013 OSAP Annual Symposium

2  **Learning objectives**

- ▶ Understand why standards matter to the US dental industry, the profession and consumers
- ▶ Find out which organizations have the greatest impact on the dental industry and profession
- ▶ Learn how regulatory agencies use standards in the US and abroad
- ▶ Learn from case studies about how dental standards can affect the development and marketing of dental products
- ▶ Learn how you or your company can become involved in ANSI and ISO standards development

3  **American National Standards Institute (ANSI)**

- ANSI's mission is to enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems.

4  **American National Standards Institute (ANSI)**

- American Dental Association (ADA)
  - Standards Committee for Dental Products (SCDP)
    - US Technical Advisory Group for ISO TC 106 (US TAG)
  - Standards Committee for Dental Informatics (SCDI)

5  **Standards Committee for Dental Products (SCDP)**

- Subcommittees
  - SC 1 Restorative materials and orthodontics
  - SC 2 Prosthodontic materials
  - SC 3 Terminology
  - SC 4 Instruments
  - SC 5 Infection Control and Safety
  - SC 6 Equipment
  - SC 7 Oral hygiene products
  - SC 8 Implants
  - SC 9 CAD/CAM

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7  **American National Standards Institute (ANSI)**

- Association for the Advancement of Medical Instrumentation (AAMI)
  - Sterilization Standards Committee
    - US TAG for ISO TC 198 Sterilization of healthcare products
    -
- ASTM International (formerly American Society for Testing and Materials)
  - ASTM standards for medical gloves
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8  **International Organization for Standardization (ISO)**

- ▶ Technical Committee 106 Dentistry (TC 106)
  - SC 1 Restorative materials and orthodontics
  - SC 2 Prosthodontic materials
  - SC 3 Terminology
  - SC 4 Instruments
  - SC 6 Equipment
  - SC 7 Oral hygiene products
  - SC 8 Implants
  - SC 9 CAD/CAM
  
- ▶ Technical Committee 198 Sterilization of Healthcare Products (TC 198)
  - AAMI is the US TAG for TC 98

9  **International Organization for Standardization (ISO)**


- ▶ Technical Committee 106 Dentistry (TC 106)
  - SC 1 Restorative materials and orthodontics
  - SC 2 Prosthodontic materials
  - SC 3 Terminology
  - SC 4 Instruments
  - SC 6 Equipment
  - SC 7 Oral hygiene products
  - SC 8 Implants
  - SC 9 CAD/CAM
  
- ▶ Technical Committee 198 Sterilization of Healthcare Products (TC 198)
  - AAMI is the US TAG for TC 98

10  **Government Impact...**

- ▶ Consensus standards are supported more and more by US, national, regional, and international governments
  - FDA recognition of voluntary consensus standards in lieu of a 510(k)
  - OMB Circular A-119 recommends government agencies adoption of voluntary consensus standards
  - National Technology Transfer Act recommends government agency adoption of voluntary consensus standards
  - A number of foreign countries require conformance with relevant ISO standards as a condition for importation
- ▶

11  **Standards for Medical Devices**

- ▶ Most industry standards address aspects of safety and/or effectiveness relevant to medical devices
- ▶ Voluntary standards are adopted by the FDA, EPA and other national regulatory bodies such as the European Commission
- ▶ Standards then move to the regulatory arena and can become mandatory

12  **ISO and CEN**

- ▶ The Vienna agreement (1991, 2001) recognizes the primacy of international standards but,
  - also recognizes that CEN may need to “undertake work which is urgent in the European context, but less so in the international one”.
  - CEN develops European Standards or “EN”
  - The agreement sets out modes for collaborative development of standards led by ISO or CEN:
  - Standards developed within one body are notified for the simultaneous approval by the other.

13  **ISO and the CE Mark**

- ▶ The CE mark is required to market a medical product to the European Community
- ▶ Medical companies must be compliant with ISO 9000 and ISO 13485: Quality Assurance standards and quality systems for the medical device industry.
- ▶ Similar to FDA GMP in US
- ▶

14  **CE Marking and notification**

- ▶
- ▶ CE marking is a declaration by the manufacturer that the product is in conformity with all applicable EEA legislation and that all appropriate conformity assessment procedures have been completed.
- ▶
- ▶ CE marking can therefore be regarded as a sort of passport for Europe, although it should be noted that it also applies to products manufactured in and for Europe.
- ▶
- ▶ CE marking is not the same as certification, because it does not always involve a third party (Notified Body).
- ▶
- ▶ CE marking is also not a proof of conformity with European standards; it is a presumption of conformity with the European Directive(s).

15  **ISO and the CE Mark**

- ▶ Conformance with ISO product standards are often required for CE mark certification
- ▶ Other non EEA countries also require the CE mark (Turkey)
- ▶

16 

17  **Case study: The high speed handpiece**

- ▶ High-Speed turbine handpieces revolutionized operative dentistry
- ▶ ISO Standardization of connectors and burs opened markets to worldwide competition and

innovation



18  **58 Current SCDP Projects**

|  | Projects |
|--|----------|
| SC 1: Filling and restorative materials            | 16       |
| SC 2: Prosthodontic Materials                      | 9        |
| SC 3: Terminology                                  | 1        |
| SC 4: Instruments                                  | 6        |
| SC 5: Infection Control, Barrier & Safety Products | 8        |
| SC 6: Dental Equipment                             | 5        |
| SC 7: Abrasives and Oral Hygiene Devices           | 6        |
| SC 8: Dental Implants                              | 0        |
| SC 9: CAD/CAM in Dentistry                         | 7        |

19  **SC5: Infection Control, Barrier and Safety Products**

20

|  | Projects |
|--|----------|
| SC 1: Restorative Materials & Orthodontic Products | 16       |
| SC 2: Prosthodontic Materials                      | 7        |
| SC 3: Terminology                                  | 6        |
| SC 4: Instruments                                  | 12       |
| SC 6: Dental Equipment                             | 7        |
| SC 7: Oral Care Products                           | 2        |
| SC 8: Dental Implants                              | 5        |
| SC 9: Dental CAD/CAM systems                       | 5        |

21  **Examples of Projects Involving Infection Control**

22  **Why are standards important to business?**

23  **What major bankruptcy of a respected pharma and medical device company was based on infections caused by their device?**

24  **Who pays attention to standards?**

- ▶ Standards bodies (ISO, ANSI, AAMI)
  - ▶ Foreign competitors-to establish advantage (suction flow rates, German steel, forceps)
  - ▶ Foreign governments-mandatory compliance in some cases
  - ▶ Academics
  - ▶ Practitioners? (Through ADA-SCDP, SCDI)
  - ▶ Purchasing agents – government, institutional
  - ▶ Litigators (gloves – standard labeling.)
  - ▶ Manufacturers (Broadly ISO QSR, individual standards.)
  - ▶ Who else?
- ▶

25  **FDA**

- ▶ Not mandatory; but,.....

- ▶ The new 510 (k)
  - ▶ Reprocessing/cleaning/disinfection/sterilization (Brief on FDA/CDC meeting)
  - ▶ Validation
  - ▶ Labeling
- 26  **Labeling**
- ▶ Unique Device Identifier - standards
  - ▶ Control
  - ▶ Harmonization
- 27  **Discussion**
- 28  **ADA SCDP:  
Current Projects**
- Subcommittee 1:  
Restorative Materials and Orthodontic Products
- 29  **Current Projects**
- Subcommittee 2: Prosthodontic Materials
- 30  **ADA SCDP:  
Current Projects**
- Subcommittee 3: Terminology
- 31  **ADA SCDP:  
Current Projects**
- Subcommittee 4: Instruments
- 32  **ADA SCDP:  
Current Projects**
- Subcommittee 5:  
Infection Control, Barrier and Safety Products
- 33  **ADA SCDP:  
Current Projects**
- Subcommittee 6: Dental Equipment
- 34  **ADA SCDP:  
Current Projects**
- Subcommittee 7:  
Abrasives and Oral Hygiene Devices
- 35  **ADA SCDP:  
Current Projects**
- Subcommittee 8: Dental Implants
- 36  **ADA SCDP:  
Current Projects**
- Subcommittee 9: CAD/CAM in Dentistry
- 37  **ISO/TC 106 Dentistry:  
Current Projects**
- Subcommittee 1: Filling and restorative materials

- 38  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 2: Prosthodontic materials
- 39  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 3: Terminology
- 40  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 4: Dental instruments
- 41  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 6: Dental equipment
- 42  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 7: Oral care products
- 43  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 8: Dental implants
- 44  **ISO/TC 106 Dentistry:  
Current Projects**  
Subcommittee 9: Dental CAD/CAM systems
- 45  **ANSI Accreditation Requires...**
  - ▶ Balance of interests
  - ▶ Open to all interested parties
  - ▶ Due process
  - ▶ Consensus documents
  - ▶ Written procedures