Ophthalmic Standards and Their Use by the FDA

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Ophthalmic standards

- American National Standards Institute (ANSI)
- International Standards Organization (ISO)

ANSI

- ANSI does not create standards itself
- Standards in particular field are created an Accredited Standards Committee (ASC)
- ANSI sets the policies and procedures with which an ASC must conform
- ANSI audits ASCs to insure compliance with policy and assists them in publishing the standards they create

Accredited Standards Committees

- An ACS is formed when a group from a specific economic or interest field is formed and asks the American National Standards Institute to accredit it to create ANSI standards in its field
- In 1956 such group was accredited as ASC Z80 to write standards in the field of ophthalmic optics
- ACS Z80 is a *voluntary, consensus* standards development organization

United States policy regarding ANSI and ISO standards

- ANSI and ISO standards are *voluntary consensus* standards
  - A voluntary consensus standard is a standard developed or adopted by voluntary consensus standards bodies, both domestic and international
  - *Voluntary* means no one has to conform to an applicable standard. But if you state you do, then you must actually do so.
  - *Consensus* means that standards are created by representatives from all areas of the field and every effort is made to get agreement on all aspects of each standard created.

ACS Z80 – 18 members

- Abbott Medical Optics (AMO)
- Advanced Medical Technologies Association
- American Academy of Ophthalmology (AAO)
- American Academy of Optometry (AAO)
- American Ceramic Society
- American Glaucoma Society
- American Optometric Association (AOA)
- American Society of Cataract and Refractive Surgery (ASCRS)
- Contact Lens Institute
- Contact Lens Manufactures Association
- Department of Veterans Affairs
- Federated Cornea Societies
- Food & Drug Administration CDRH (FDA)
- National Association of Optometrists & Opticians
- Optical Laboratory Association
- Opticians Association of America
- Sunglass Association of America
- The Vision Council
- U.S. ISO TC 172/SC7

ISO

- ISO forms Technical Committees (TC) and, within them technical Sub-Committees (SC), that create ISO standards
- In 1979 an International Standards Organization Technical Committee was formed to create standards in all fields of optics - ISO/TC172
- In 1980 the first sub-committees were formed within ISO/TC172 to create standards in the field of ophthalmic optics had their initial meetings
- Today all ISO Standards in the field of ophthalmic optics are created within ISO/TC172/SC7

Involvement of the FDA in ANSI and ISO standards

- Federal Food, Drug and Cosmetics Act (1938)
  - FD&C Act
- Medical Device Amendments of 1976 to the FD&C Act
  - USC 514
- Safe Medical Device Act of 1990
  - Promulgation of mandatory standards at Agency's discretion
- National Technology Transfer and Advancement Act (NTTAA) of 1995
  - Encourages Agency participation in voluntary consensus standards bodies
- FDA Modernization Act of 1997
  - Revised Section 514(c)
  - Added ability to formally recognize a standard, "all or in part"
  - Added the ability to accept a formal Declaration of Conformity

US National strategy on the use of standards

- Passage of the National Technology Transfer and Advancement Act (NTTAA) of 1995
- Grew out DoD's experience of relying more on voluntary consensus standards and less on Military Specifications (MIL SPECs)
- Directs Federal Agencies to adopt private sector standards in lieu of creating proprietary, non-consensus standards
- Encourages Agency participation in voluntary consensus standards bodies

See circular OBM A-119 2/10/1198

21 USC Section 514(c)

- (c) Recognition of standard
  - (1)
    - (A)..."by publication in the FR, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket requirement or other applicable requirement under this chapter to which such standard is applicable"
    - ((B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter.
  - (2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter.

What *recognize* means to the FDA

- The term "recognize" in section 514(c) of the FD&C Act refers to FDA's identification of standards as appropriate for manufacturers of medical devices to declare conformance to meet relevant requirements in the FD&C Act, including premarket submission requirements.

Types of *recognition*

- When the FDA recognizes a standard this recognition can come in two forms
  - The standard can be recognized completely, with the words, "complete standard" or "complete standard and any annexes”
  - The standard can be recognized in part, with the words, "complete standard with the following exceptions: (clauses are then listed in order of how they appear in the standard)

Supplemental Information Sheet (SIS)

- Found by going the FDA website for recognized standards and selecting the standard of interest
- When information on the selected standard is displayed, the Supplementary Information is found in Part B of the document

FDA policy on the use of recognized standards

- Be aware, the use of consensus standards generally satisfies only one part of a premarket submission
- It may not, on its own, provide sufficient basis for a regulatory decision
- It usually does not satisfy all the required elements of a submission
- FDA recognition of a standard does not supersede other aspects of the FD&C Act and its implementing regulations for marketing or investigating medical devices in the US.

Areas in which the FDA allows the use of recognized standards

- Premarket Submissions
  - Traditional 510(k)
  - Abbreviated 510(k)
  - Special510(k)
  - *de novo* (novel devices of low to moderate risk)
  - IDE (Investigative Device Exemption)
  - PMA/PDP (Premarket Approval/Product Development Protocol)
  - HDE (Humanitarian Device Exemption)
  - Q Submission

Use in 510(k) Submissions

- In 510(k) submissions, conformance to a recognized consensus standard may help establish substantial equivalence of a new device to a predicate device.
- This information may be used to show that the new device is as safe and effective as the predicate in the area(s) covered by the standard.

Declaration of Conformity (DoC)

- Used for FDA-recognized standards
- Certification that the device conforms to all of the requirements of an FDA-recognized standard
- In a DoC a submitter may not deviate from the FDA-recognized standard

FDA recognized standards for intraocular lenses (IOLs)

ANSI	ISO
Z80.7 Intraocular lenses*	11979-1 IOLs Vocabulary *
	11979-2 IOLs Optical properties and test methods
	11979-3 IOLs Mechanical properties and test methods
	11979-5 IOLs Biocompatibility
	11979-6- IOLs Shelf-life and transport stability
	11979-7 IOL Clinical investigations
	11979-8 IOL Fundamental requirements *
	11979-9 IOLs Multifocal intraocular lenses
	11979-10 IOLs Phakic intraocular lenses

* one clause not recognized

What does *recognized* mean specifically for IOLs?

- At present there is only 1 guidance document in existence for IOLs
- To fill the place of IOL guidance documents the FDA *recognizes* that sections of recognized IOL standards can be used in place of FDA guidance documents to give guidance for certain aspects of IOL premarket approval process

What type of guidance do IOL recognized standards give?

- IOL recognized standards generally have informative clinical protocol annexes
- These annexes have been created with the active participation of FDA personnel
- The FDA recognizes that these clinical protocol annexes give guidance for conducting the necessary clinical studies needed to support premarket approval

What type of guidance do IOL recognized standards give?

- IOL recognized standards give methods for measuring various critical optical and mechanic properties of IOLs
- These methods have been created with the active participation of FDA personnel
- The FDA recognizes that these methods can be used to measure the various parameters needed to support premarket approval of IOLs

Normative and Informative portions of a standard

- Normative portions are those that must be complied with to claim compliance with the standard
  - The main body of a standard only contains normative sections
  - Annexes can be normative
- Informative portions do not have to followed to comply with the standard
  - Only Annexes can be informative

FDA approach to normative and informative portions of a recognized standard

- Normative portions
  - To submit a Declaration of Conformance (DoC) the device must comply with the requirements of all normative portions of the standard
- Informative annexes
  - Informative annexes, in particular clinical informative annexes, are considered by the FDA to be guidance documents

Thank you for your attention