FDA’s Use of Voluntary Consensus Standards

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Outline

CDRH Mission, Vision, Values

Why Are Standards Important?

Legislative Authorities

CDRH Standards Program

Agency’s Use of Standards

The Value of International Medical Device Standards in the 21st Century
Mission & Vision of CDRH

• The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health.

• Patients have access to high-quality, safe, and effective medical devices of public health importance first in the world.
SHARED VALUES

• **Public Health Focus** - We focus on activities and outcomes that protect and promote public health.

• **Science-Based Decisions** - We make decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.

• **Our People** - Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.

• **Innovation** - We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.

• **Transparency** - We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.

• **Honesty and Integrity** - We maintain the public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.

• **Accountability** - We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them.
Brief Overview of FDA

FDA uses regulations and product standards as the "yardsticks" that define specific requirements manufacturers follow to assure product safety and to provide accurate information to health professionals and consumers.
Medical Device Regulatory Framework is Based on Risk

Medical Device Classes:

**Class I**
General Controls
Most exempt from premarket submission

**Class II**
Special Controls
Premarket Notification [510(k)]

**Class III**
Premarket Approval
Premarket Approval Application [PMA]

Additional Classification:

**De Novo**
Device "types" that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood

**Humanitarian Device Exemption (HDE)**
Devices for orphan diseases intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the United States

The Value of International Medical Device Standards in the 21st Century
Why Are Standards Important?

- Gives agencies discretion to use standards (other than FDA standards)
- Builds consistency, credibility, and predictability
- Integral in the execution of the FDA mission:
  - Performance characteristics
  - Testing methods
  - Manufacturing practices
  - Product specific standards
  - Scientific protocols
  - Compliance criteria
  - Statistical methods
  - Labeling
  - Risk assessment
Why Are Standards Important?

- Greater potential to save time and money over FDA development of technical standards
- Open participation by affected parties
- Minimize or eliminate inconsistent standards internationally
- Can lead to international harmonization on issues
Why Are Standards Important?

• Often represents leading-edge thinking on an issue

• Because standards are being updated and revised on a rigorous schedule, the most current thinking about safety and effectiveness will be included when these standards are cited.
US Organizational Relationships to International Standards (ISO & IEC)

ISO or IEC

Technical Committee / Subject Area

U.S. Technical Advisory Group (TAG) and Its Administrator

U.S. Member of ISO and IEC (via USNC)
Who can participate in Standards Development?

All stakeholders directly and materially affected by the document

- National activities (including mirror committees for international projects)—any organizations, company, government agencies or individual materially affected.

- International activities—National member bodies and their officially appointed representatives. International meetings are closed to the public; only appointed experts attend.
How Do U.S. Stakeholders Get Involved?

• Via U.S. Technical Advisory Groups (TAGs)
  – These are the U.S. mirror committees that do the work at the domestic and international levels
  – U.S. TAGs to IEC are approved by the USNC, and U.S. TAGS to ISO are accredited by ANSI; they must follow the Institute’s cardinal principles of openness, balance, due process, and transparency

• Decisions are consensus-based

• Membership is open to all materially affected U.S. parties

  – The TAG Administrator is the organization officially assigned to provide administrative support to the TAG for a designated period
U.S. TAG Roles and Responsibilities

- Formulate U.S. positions and proposals on all technical and administrative matters, and interface with IEC or ISO
  - Determine U.S. votes and comments on all documents (draft international standards, technical reports, etc.)

- Provide adequate U.S. representation to IEC/ISO meetings
  - Designate U.S. delegates, heads of delegation, and experts for IEC and ISO Technical Committee (TC) and Subcommittee (SC) meetings
  - Appoint experts to serve on Working Groups (WGs), Maintenance Teams (MTs), and Project Teams (PTs)
  - Ensure compliance with the ANSI “Guide for U.S. Delegates to IEC/ISO Meetings”
Brief Overview of FDA/CDRHs involvement with IEC and ISO

12 Technical Committees + several subcommittees

~60 WGs

17 Technical Committees + several subcommittees

~140 WGs

CDRH is also a member to ~400 working groups across ~20+ Standard Developing Organizations

The Value of International Medical Device Standards in the 21st Century
Why Is Government Participation So Important?

- Ability to influence international standards that:
  - Are frequently conditions of international commerce that have a direct impact on country’s competitiveness and national priorities
  - May be adopted by regulators or affect regional and national regulatory policies
- Promote the development of standards that facilitate and shape innovation in ways that are advantageous to a country’s interests
- Initiate new standards that are relevant to your mission and priorities
- Engage with a wide range of stakeholders at the domestic and international levels
  - Opportunities for technical and policy discussions with industry experts, international counterparts, regulators and policy makers, NGOs
  - Build relationships and partnerships of mutual benefit

The Value of International Medical Device Standards in the 21st Century
Why Is Government Participation So Important? (continued)

- Play a key role in developing country positions and advocate for them at the international level
- Help to establish even stronger country participation and leadership within ISO and IEC to balance the other voices that are gaining strength
  - China, India, Korea, and others have been bolstering their efforts to get more involved in ISO and IEC
Early involvement is key to getting your voice heard!

Stability of content

Opportunity to change

Proposal & first draft
Committee Draft
Last stage & Final vote

NWIP
CD
DIS = FDIS

ISO
Bottom Line: Participation Is Key

- IEC and ISO standards have definite impact on a country’s competitiveness, markets, and regulations
- Standards that affect your organization’s mission will be written with or without your participation
- To influence outcomes, you need to be involved
- Active engagement is well worth the investment
How this all works -

NIST
NTTAA
OMB Circular A-119
FDA Standards Participation
FDA Staff Manual Guide
CDRH Standards Participation
USC 514
NIST

National Institute of Standards and Technology

Assigned responsibility to coordinate federal, state, and local technical standards and conformity assessment activities, as well as coordinating with those in the private sector. Manages the Commerce Standards Committee and coordinates the activities of the Interagency Committee on Standards Policy (ICSP).
National Technology Transfer and Advancement Act of 1995 (NTTAA)

- Directs Federal Agencies to adopt private sector standards in lieu of creating proprietary, non-consensus standards
- Encourages participation in voluntary consensus standards bodies
- Directs NIST to coordinate Federal, State, and Local governments to have greater reliance on voluntary standards and decrease dependency on in-house standards
OMB Circular A-119

• Sets forth requirements for:
  – Agency participation
  – Annual reporting
  – “Incorporation by reference” of standards into regulation
OMB Circular A-119

Goals

• Eliminate unnecessary Government costs
• Provide incentives that serve national and global market needs
• Encourage long-term growth for the US
• Promote economic competition
FDA Participation in Standards

- 21 CFR 10.95, Participation in outside standard-setting activities

- FDA Policy on Standards “Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines”, 60 FR 53078 (Oct. 11, 1995).
Standards at FDA

• SMG 9100.1 FDA Staff Manual Guides, Volume IV – Agency Program Directives
  – Policies of each Center in FDA
  – Development and Use of Standards
  – Definitions
  – Roles/Representation
• Where can I find the SMG?
  – http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm193332.htm
CDRH Standards Management Staff:

What do we do and why?
Standards in CDRH

• Medical Device Amendments of 1976
  – USC 514

• Safe Medical Device Act of 1990
  – Promulgation of mandatory standards at the Agency’s discretion

• FDA Modernization Act of 1997
  – Revised 514c
  – Added ability to formally recognize standard, “all or in part”
  – Added ability to accept a formal Declaration of Conformity
Standards in CDRH

• FDA Modernization Act of 1997 – Section 514(c)
  – Added ability to formally recognize standard, “all or in part”
  – Added ability to accept a formal Declaration of Conformity
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”
21 USC 514(c) – cont’d

(1)(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.
21 USC Section 514(c) – cont’d

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

– (i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

– (ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.
CDRH Standards
Management Staff:
What do we do and why?
CDRH Standards Program - Standards Management Staff

Created as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. Although CDRH had been involved in the development of medical device standards for decades, FDAMA formalized the process.

- The Standards Program is a regulatory support activity consisting of cross-office teams within CDRH and FDA.
- Work closely with the Standards Developing Organizations (SDOs)
- Advertise standards liaison representative positions
- Facilitate a Center recommendation a particular standards activity,
- Maintain standards databases
- Provide access to established standards for all CDRH staff.
- Update currently recognized standards and coordinate recognition of new national and international voluntary consensus standards for medical devices and radiation-emitting electronic products.
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition

- Recognition typically 2-3x’s a year (Spring and Fall)
- Initiation: Anyone from the CDRH/FDA (even from outside the agency) can recommend a national or international consensus standard for consideration of recognition
- Screening: The STG discusses each recommended standard for its appropriateness for recognition. Each office provides its perspective in terms of its merits and/or concerns – a consensus process
- Scientific discussion: Discussion among a broader audience (outside the Center, inter-offices within CDRH, special working groups etc.) focusing on the science and details – anything that causes safety/effectiveness concerns should be excluded from the recognition
- Loop: The above process repeats as many times as necessary until fully discussed
- Supplemental information sheet is prepared and technical contact person is identified
- Proceed with recognition paperwork for the Federal Register
FDA/CDRH Standards Program

- 17 Specialty Task Groups (STGs) Covering 23 different Scientific/Device areas.
- Participate in ~ 590* national and international committees
- ~ 370 staff participating in standards development
- ~ 1050 currently recognized standards
- 2-4 recognition cycles per year

* Typically see a 5-10% increase in requests for new standards development activities each year.
Specialty Task Groups (STGs)

- Anesthesia
- Biocompatibility
- Cardiovascular
- Dental & ENT
- Neurology / Physical Medicine
- General I (RM/QS/HF)
- General II (ES/EMC)
- General Hospital & General Plastic Surgery
- Nanotechnology
- OB GYN GU
- Ophthalmic
- Orthopedic
- Radiology
- Software, IT
- Sterility
- InVitro Diagnostics
- Materials / Tissue Engineering
Specialty Task Groups

Center-wide participation for Center perspective
- Office of Office of Compliance (OC)
- Office of Communication, Education (OCE)
- Office of Device Evaluation (ODE)
- Office of Science and Engineering Labs (OSEL)
- Office of Surveillance & Biometrics (OSB)
- Office of In Vitro Diagnostics & Radiology (OIR)

Agency and Dept. participation includes CBER, ORA etc...
Standards Utilization & Guidance

- CDRH believes that conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices.

- Therefore, information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made for Investigational Device Exemptions (IDE), Humanitarian Device Exemptions (HDE), Premarket Approvals (PMA), and Product Development Protocols (PDP).
Standards Utilization & Guidance

• 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.
Conformance

Conformance ≠ Equivalence
Conformance ≠ Clearance
Conformance ≠ Approval
Conformance

• Falsifying a declaration is a prohibited act under 21 USC 331(x)
• Any device for which a declaration of conformity has been falsified is adulterated under 21 USC 351(e)(2)
Premarket Utilization

• In 510(k) submissions in particular, conformance to a recognized consensus standard may help establish the 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 areas covered by the standards.
Premarket Utilization

• Consensus standards are very useful when a recognized standard exists that serves as a **complete** performance standard for a specific medical device.

• Comprehensive consensus standards are rare.

• Conformance with a particular recognized consensus standards may not always be a sufficient basis for regulatory decisions.
# CDRH Standards Program

## Periodic Table of Recognized Standards

To See 1000 More Recognized Standards Visit:

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm)

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1. **H**
   - Hypodermic Needles for Single Use
   - ISO 505-2

2. **Li**
   - Laboratory Information Systems
   - CLSI LS03-A

3. **Be**
   - Bacterial Endotoxin Test Methods
   - AAMI ST 72

4. **Mg**
   - Magnetic Resonance Imaging
   - IEC 60021-2-3

5. **Ca**
   - Magnetic Resonance Imaging
   - IEC 60021-2-3

6. **Sc**
   - Subcutaneous Screening Test for Implants
   - ASTM F876-08

7. **Ti**
   - Implants for Surgical Titanium
   - ASTM F876-02

8. **V**
   - Implants for Surgical Titanium
   - ASTM F876-02

9. **Cr**
   - Implants for Surgical Chromium
   - ASTM F876-02

10. **Mn**
    - Micrometer Assays in Bone Marrow
    - ASTM E2096-97

11. **Fe**
    - Febrile Temperature Screening
    - ASTM E2096-97

12. **Co**
    - Coating Iodine Visible Light Dye
    - ASTM E2096-97

13. **Ni**
    - Nitrile Gloves for Medical Use
    - ASTM D6319

14. **Cu**
    - Curing Units Visible Light Dye
    - ASTM E2096-97

15. **Zn**
    - Zinc Dye Commodities
    - ASTM E2096-97

16. **Ga**
    - Gamma Radiation Facilities
    - ISO 51702

17. **Ge**
    - Genetics and Oncology
    - IEC MM01-A1

18. **As**
    - Acrylic Processing
    - IEC 14308-02

19. **Se**
    - Segmental Algorithms and Reporting
    - ASTM E2096-97

20. **Br**
    - Biological Reactivity Test
    - USP <87>

21. **Kr**
    - Knee Replacement Prosthetics
    - ASTM F2085-12

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22. **Rb**
    - Anesthetic Reservoir Bags
    - ISO 5162

23. **Sr**
    - Stability Testing of IVI Reagents
    - ISO 13640

24. **Yb**
    - Yeast Anti-Fungal Testing
    - ASTM F1413-06

25. **Zr**
    - Wrought Zirconium ASTM
    - ASTM F1413-06

26. **Nb**
    - Non-Invasive Blood Pressure
    - ISO 80601-0

27. **Mo**
    - Technical Corrugated Packer
    - ISO 5841-4

28. **Ru**
    - Rubber Surgical Glove Specifications
    - ASTM D3757

29. **Rh**
    - Pediatric Bronchoscopy
    - ASTM D3757

30. **Ag**
    - Accelerated Aging ASTM
    - ASTM F1890-07

31. **Cd**
    - Cardiac Defibrillators
    - ASTM F1890-07

32. **In**
    - Inflow Equipment
    - ISO 8356-3

33. **Sn**
    - Signal-to-Noise Ratio
    - ISO 11318

34. **Sb**
    - Segments of Bone Defects
    - ASTM F2211

35. **Te**
    - Tissue Engineering Products
    - ASTM F2211

36. **I**
    - Intravascular Lenses
    - ASTM F2211

37. **Xe**
    - Extraction of Medical Plastics
    - ASTM F750-87

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38. **Cs**
    - Circulatory Support Devices
    - ISO 14085-5

39. **Ba**
    - Blood Alcohol Testing
    - CLSI T/MB06-A

40. **Lu**
    - Lu-Lu Laser Product Safety Requirements
    - ISO 61823-1

41. **La**
    - Human Factors Engineering
    - ASTM F2258

42. **Pr**
    - Photographic Materials
    - ISO 7286-0

43. **Nd**
    - Photographic Materials
    - ISO 7286-0

44. **Sm**
    - Photographic Materials
    - ISO 7286-0

45. **Eu**
    - Photographic Materials
    - ISO 7286-0

46. **Gd**
    - Photographic Materials
    - ISO 7286-0

47. **Tb**
    - Tuberculosocid Activity of Diagnostics
    - ISO 7286-0

48. **Dy**
    - Dyne Heat Steels
    - AAMI ST50

49. **Ho**
    - Home Use IEC
    - ISO 60061-1-11

50. **Er**
    - Tumor Heat Steels
    - IEC 60611-1-11

51. **Lu**
    - Lubricant Compressibility
    - ASTM D7661-10

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