FDA’s Use of Voluntary Consensus Standards

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Today’s Topics

1. Mission, Vision, Regulation
2. Why Are Standards Important?
3. Key Legislation and Goals
4. CDRH Standards Program
5. Agency’s Use of Standards and Guidance
Mission & Vision of CDRH
The mission of the Center for Devices and Radiological Health (CDRH) is to:
- Protect and promote the public health
- Ensure patients have access to high-quality, safe, and effective medical devices of public health importance first in the world
FDA Use of Regulation

- FDA uses regulations and product standards as the “yardsticks“ to:
  - Define specific requirements manufacturers follow to assure product safety
  - Provide accurate information to health professionals and consumers

- The medical device regulatory framework is based on RISK
Section 2

Why are Private Sector Standards Important?
Private Sector Standards Are Important

- Gives agencies discretion to use standards (other than FDA standards)
- Builds consistency, credibility, and predictability
- Integral in the execution of the FDA mission
- Greater potential to save time and money rather than FDA development of technical standards
- Open participation by affected parties
- Minimizes or eliminates inconsistent standards internationally
- Can lead to international harmonization on issues
- Often represents leading-edge thinking on an issue
Section 3

Legislative Goals
Legislative Goals

- Eliminate unnecessary government costs
- Provide incentives that serve national and global market needs
- Encourage long-term growth for the US
- Promote economic competition
Directs Federal Agencies to:

- Adopt private sector standards in lieu of creating proprietary, non-consensus standards
- Participate in voluntary consensus standards bodies
Sets forth requirements for:

- Agency participation
- Annual reporting
- “Incorporation by reference” of standards into regulation
CDRH Standards Program

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 a standard, “all or in part”
  - Added ability to accept a formal Declaration of Conformity
Standards Management Program

Created by Food and Drug Administration Modernization Act (FDAMA) of 1997.

The Standards Program
- Is a regulatory support activity consisting of cross-office teams
- Works closely with the Standards Developing Organizations (SDOs)
- Advertises standards liaison representative positions
- Facilitates Center recommendations on particular standards
- Maintains standards databases
- Provides all CDRH staff access to established standards
- Updates currently recognized standards, coordinates recognition of new national and international voluntary consensus standards for
  - Medical devices
  - Radiation-emitting electronic products
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

- Conduct two to four recognition cycles per year

* Typically see a 5-10% increase in requests for new standards development activities each year
Identification and Evaluation of Candidate Consensus Standards for Recognition

Typically two to three times per year (Spring and Fall), incorporates several steps

- Initiation
- Screening
- Scientific discussion
- Loop
- Supplemental information sheet preparation and technical contact identification
- Recognition of paperwork
CDRH believes that:

- Conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness

- 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)
  - Product Development Protocols (PDP)
Standards Utilization & Guidance

- The use of consensus standards **generally satisfies only one part** of a premarket submission
  - It usually does not satisfy all the required elements of a submission

- It may not, on its own, provide sufficient basis for a regulatory decision

- FDA recognition of a standard does not supersede other aspects of the FD&C Act
  - Nor its implementation, regulations for marketing, or investigation of medical devices in the US.
Premarket Utilization

- Consensus standards are very useful when a recognized standard, that serves as a complete performance standard for a specific medical device, exists

- Comprehensive consensus standards are rare

- Conformance with a particular recognized consensus standards may not always be a sufficient basis for regulatory decisions
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Thank you

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