Standards: Resources and Use in Premarket Submissions

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Learning Objectives

• Locate FDA-recognized standards
• Find FDA guidances on the use of standards
• Identify and decipher a standards title
• Locate standards Supplementary Information Sheet (SIS)
• Discuss the two main ways to use standards
• Describe the elements of a Declaration of Conformity (DoC) and how it’s used
Not all Standards are the Same

• Each standard developing organization (SDO) produces different types of standards
  – e.g., objective performance criteria, guidelines, practices

• Knowing the type of standard will guide the information needed in a submission
FDA Recognized Consensus Standards Database

- Repository for recognized standards
- Publicly available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- Supplementary Information Sheet (SIS)
  - provided for each recognized standard
  - identifies the device types addressed by the standard
- May be used with or without a Declaration of Conformity
Recognized Consensus Standards

The CDRH Standards Program:
- Created as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The Standards Management Staff (SMS) is responsible for facilitating the recognition of national and international medical device consensus standards.
- Modifications to the list of recognized consensus standards: Publications in the Federal Register to the list of recognized consensus standards can be accessed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/frcm123782.htm.
- Please note that changes to the recognized consensus standards database are updated the following Monday.

Learn More...

Search Database

Standards Organization
Standard Designation Number
Note: numbers only, e.g., 14971, 600611
Standards Title or Keywords
Note: do not include standard designation number
Specialty Task Group Area
Product Classification
Product Code
Note: for vertical standard searches
Type of Standard
Use ctrl button with mouse click to select up to 3 types, e.g., horizontal, national, materials specification

All Standards Organizations

All Categories

All Standard Types

FR List Publication Date

Sort By

Product Area, Item #

Quick Search

Clear Form

Search
Search Capabilities

- Standards Organization
- Standard Designation Number
- Standards Title or Keywords
- Specialty Task Group Area
- Product Classification/Product Code
- Regulation Number
- Type of Standard
- FR List Publication Date
- Sort Feature
Sample Search: Cardiovascular
Recognition List Number: 034 FR Publication Date: 01/30/2014

Part B: Supplementary Information


Date of Standard: 2007.

Addresses of Standards Development Organizations:

Association for the Advancement of Medical Instrumentation (AAMI)
4301 North Fairfax Drive
Suite 301
Arlington, VA 22203

American National Standards Institute (ANSI)
25 West 43rd Street
4th Floor
New York, NY 10036

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH-1211 Geneva 20, 0

CDRH Office and Division associated with recognized standards:

OFFICE OF DEVICE EVALUATION (ODE)
DIVISION OF CARDIOVASCULAR DEVICES (DCD)

Devices Affected:
Manual (non-automated) Non-invasive Blood Pressure Monitors and Blood Pressure Cuffs

Processes Affected:
510(k)

Type of Standard:
International, Vertical

Extent of Recognition:
Complete standard

Related CFR Citations and Product Codes:

<table>
<thead>
<tr>
<th>Regulation Number</th>
<th>Device Name</th>
<th>Device Product Class Code</th>
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</thead>
<tbody>
<tr>
<td>21CFR 1138</td>
<td>Blood Pressure Cuff</td>
<td>Class 2, 030</td>
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</tbody>
</table>

Relevant Guidance:
Non-invasive Blood Pressure (NIBP) Monitor Guidance (Version 1.0 Issued March 10, 1997)

FDA Technical Contacts:

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* In the United States, copies of this standard can be obtained from:
American National Standards Institute (ANSI)*
25 West 43rd Street
4th Floor
New York, NY 10036
SIS

• CDRH’s determination of how a standard should be used in a premarket submission or other Center process

• Built-in latitude to support a standard, even if some aspect conflicts with Agency position

• Standard may still be useful to the rest of the world even if not directly useful in review (practice guidelines)
Information on a SIS

- Recognition List Number and FR Publication Date
- Recognition Number, Designation and Title
- Date of the Standard
- Parallel Adoptions (if any)
- Scope
- Rationale for Recognition
- Extent of Recognition
- Transition (if implemented)
- Related CFR Citations and Product Codes
- Relevant Guidance(s)
- FDA Technical Contact(s)
- SDO Address
- History of Recognition
<table>
<thead>
<tr>
<th>SDO</th>
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<tr>
<td>IEC</td>
<td>60601-2-13</td>
<td>Edition 3.1</td>
<td>2009-08,</td>
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<td>Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems</td>
<td></td>
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</tbody>
</table>

Title
National Standards Title

AAMI/ANSI  BP22:1994 (R) 2011,
Blood pressure transducers
U.S. Parallel Adoption

SDO

Standards designation number

Origin
US Adoption
Reaffirmation

Title

Cardiovascular Implants – Tubular Vascular Prosthesis
Standards Guidances

- Recognition and Use of Consensus Standards
- Use of Standards in Substantial Equivalence Determinations
- Frequently Asked Questions on Recognition of Consensus Standards
Two Ways to Use a Standard in Submissions

1. General Use
2. Declaration of Conformity
General Use

- When standards are used/cited without a declaration of conformity
- Applies to any standard whether or not it is recognized
- Supported by submission of a full test report
- May use for any type of submission
  - e.g., 510(k), PMA, HDE, IDE, *De Novo*
Declaration of Conformity (DoC)

• Submitter certifies that device conforms to applicable requirements of FDA-recognized consensus standards

• Not applicable:
  – deviates from FDA-recognized standard
  – standard not recognized by FDA
Elements of a DoC

- Name and Address
- Product/device identification
- Statement of Conformity
- List of Standards and FDA recognition number
Elements of a DoC

• Date and Place of Issuance
• Signature, printed name of responsible person
• Any limitation of the Declaration of Conformity

See: ISO 17050-1 Conformity Assessment – Supplier’s declaration of conformity – Part 1: General requirements
Purpose of a DoC

• Meet certain premarket requirements
• Reduce amount of supporting data and information submitted to FDA
• Certify that the device *was* tested, and
  – conforms with the FDA-recognized consensus standard
Submission of DoC

• DoC is sufficient in some cases

• Appropriate for standards with:
  – Test method
  – Test specifications with pass/fail criteria
  – Pre-specified testing requirements or outcomes
DoC with Supporting Documentation

- Some standards require DoC and supporting documentation
- Examples of applicable standards:
  - Guidelines or Practices
  - Technical Reports
  - Technical Information Reports
- Provide options for methods or lack details (e.g., pass/fail criteria)

See: ISO 17050-2 *Conformity assessment – Supplier’s declaration of conformity – Part 2: Supporting documentation*
Key Considerations for Supporting Documentation

• Standards often provide options or choices
  – more than one method may be able to assess the device

• Submission should explain:
  – how the standard was used
  – how it was adapted or modified to fit the device

• Was the device modified to fit the standard?
• Was the final finished device tested or not and why?
Promissory Statement

• Testing has not been completed at time of submission
• Submitter promises to complete specific testing prior to marketing device
• In limited cases, FDA may accept a promissory statement
• A promissory statement is not a DoC
• Test conditions and acceptance criteria need to be described
Summary

1. We reviewed how to find FDA-recognized standards in the standards database found on the FDA website
2. We provided links to relevant guidances for standards
3. We reviewed the anatomy of a standards title
4. We reviewed the Declaration of Conformity
5. We discussed where standards may be used, including the use of promissory statements
Industry Education: Three Resources for You

1. CDRH Learn: Multi-Media Industry Education
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices
   
   www.fda.gov/Training/CDRHLearn

2. Device Advice: Text-Based Education
   - comprehensive regulatory information on premarket and postmarket topics
   
   www.fda.gov/MedicalDevices/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE