Standards: Resources and Use in Premarket Submissions

Jianchao Zeng
Senior Standards Advisor, Standards Management Staff
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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

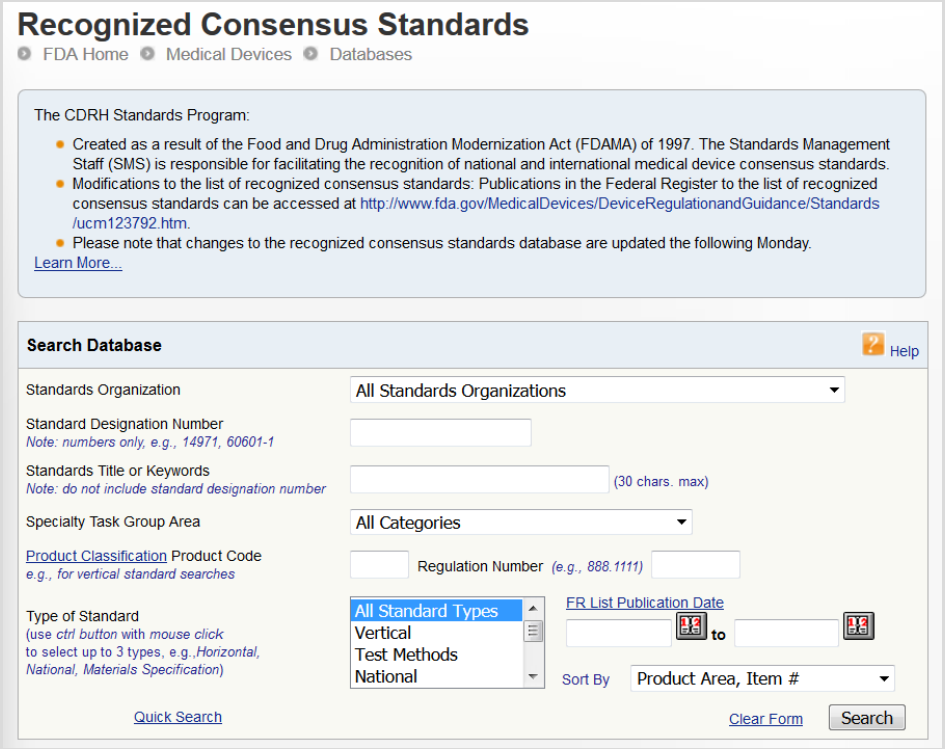
- Each standard developing organization (SDO) produces different types of standards
  - e.g., objective performance criteria, guidelines, practices

- 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

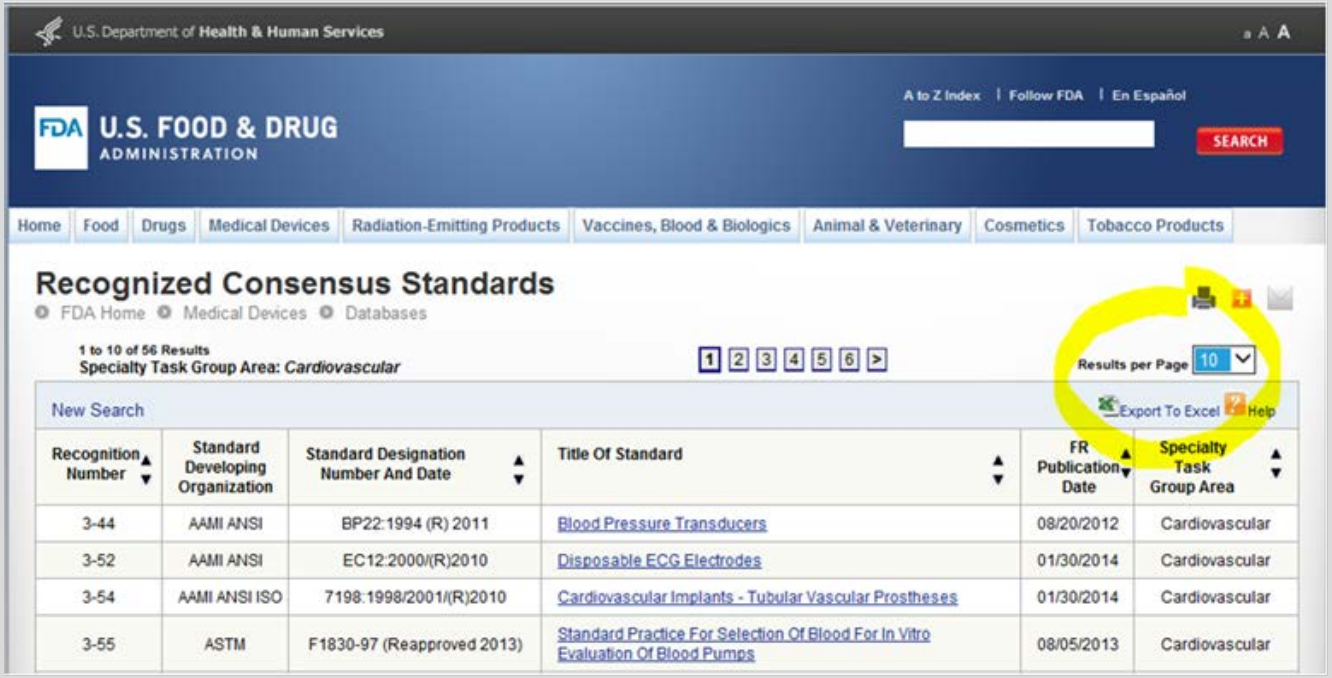
Consensus Standards Database



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



U.S. Department of Health & Human Services

A to Z Index | Follow FDA | En Español

U.S. FOOD & DRUG ADMINISTRATION

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Recognized Consensus Standards

FDA Home > Medical Devices > Databases

1 to 10 of 56 Results
Specialty Task Group Area: *Cardiovascular*

1 2 3 4 5 6 >

Results per Page 10

New Search

Export To Excel | Help

Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
3-44	AAMI ANSI	BP22:1994 (R) 2011	Blood Pressure Transducers	08/20/2012	Cardiovascular
3-52	AAMI ANSI	EC12:2000/(R)2010	Disposable ECG Electrodes	01/30/2014	Cardiovascular
3-54	AAMI ANSI ISO	7198:1998/2001/(R)2010	Cardiovascular Implants - Tubular Vascular Prostheses	01/30/2014	Cardiovascular
3-55	ASTM	F1830-97 (Reapproved 2013)	Standard Practice For Selection Of Blood For In Vitro Evaluation Of Blood Pumps	08/05/2013	Cardiovascular

Recognition List Number: 034 **FR Publication Date:** 01/30/2014

Part B: Supplementary Information

Recognition Number 3-80: AAMI / ANSI / ISO 81060-1:2007/(R)2013, Non-invasive Sphygmomanometers - Part 1: Requirements And Test Methods For Non-automated Measurement Type. (Cardiovascular)

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:

Regulation Number	Device Name	Device Class	Product Code
§870.1120	Blood Pressure Cuff	Class 2	DXQ

Relevant Guidance:

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

FDA Technical Contacts:

Charles Ho
FDA/OMPT/CDRH/ODE/DCD
10903 New Hampshire Avenue WO66, RM1318
Silver Spring MD 20993
301/796-6320
email: charles.ho@fda.hhs.gov

Sandy Weininger
FDA/OMPT/CDRH/OSEL
10903 New Hampshire Avenue WO62 RM1210
Silver Spring MD 20993
301/796-2582
email: sandy.weininger@fda.hhs.gov

*** 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

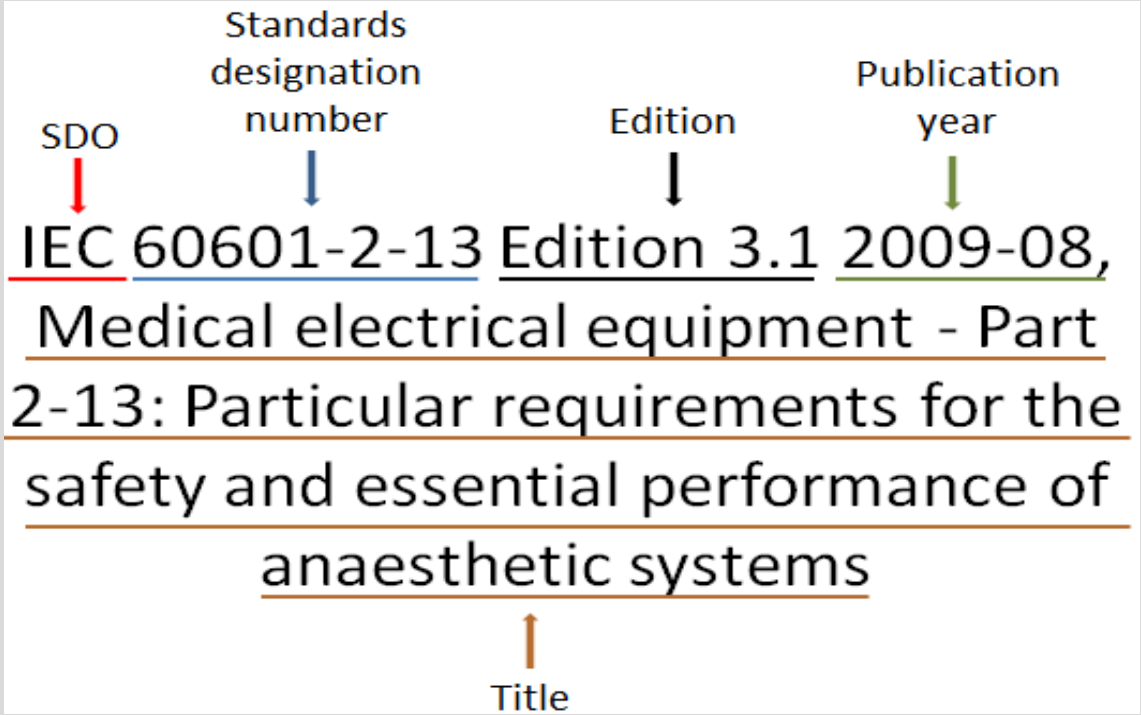
SIS

- 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)

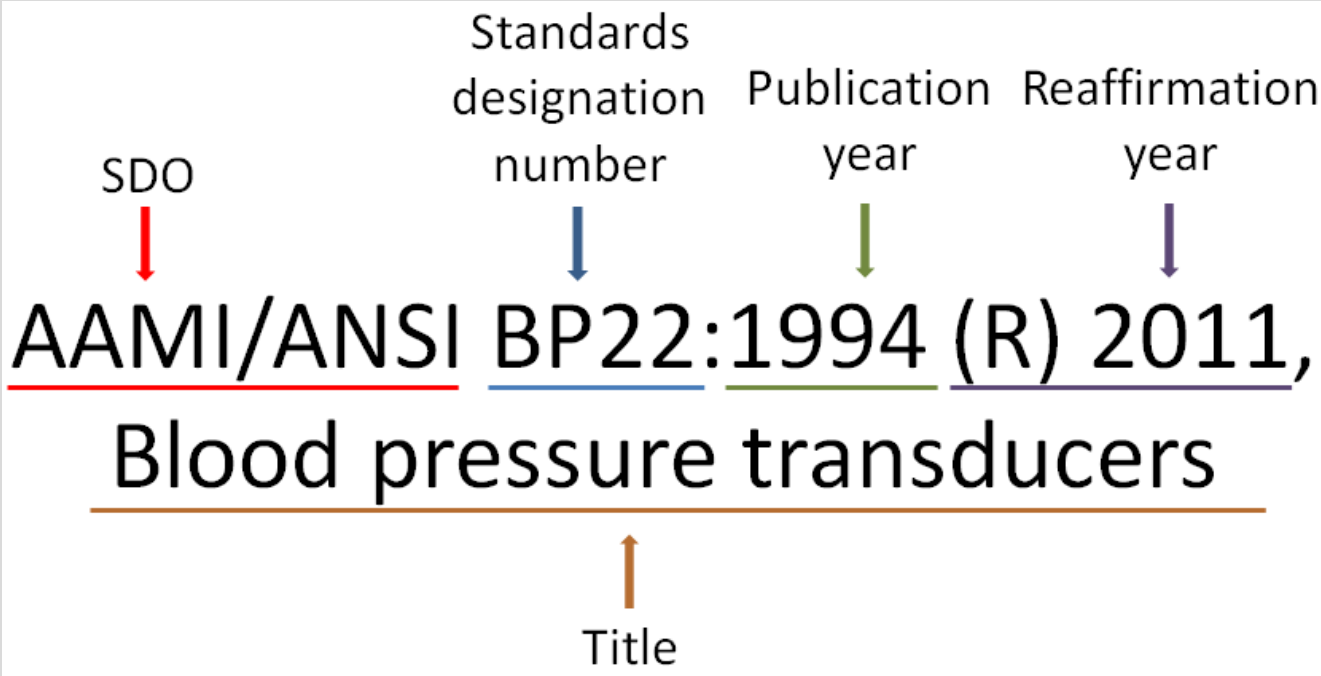
Information on a SIS

- 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

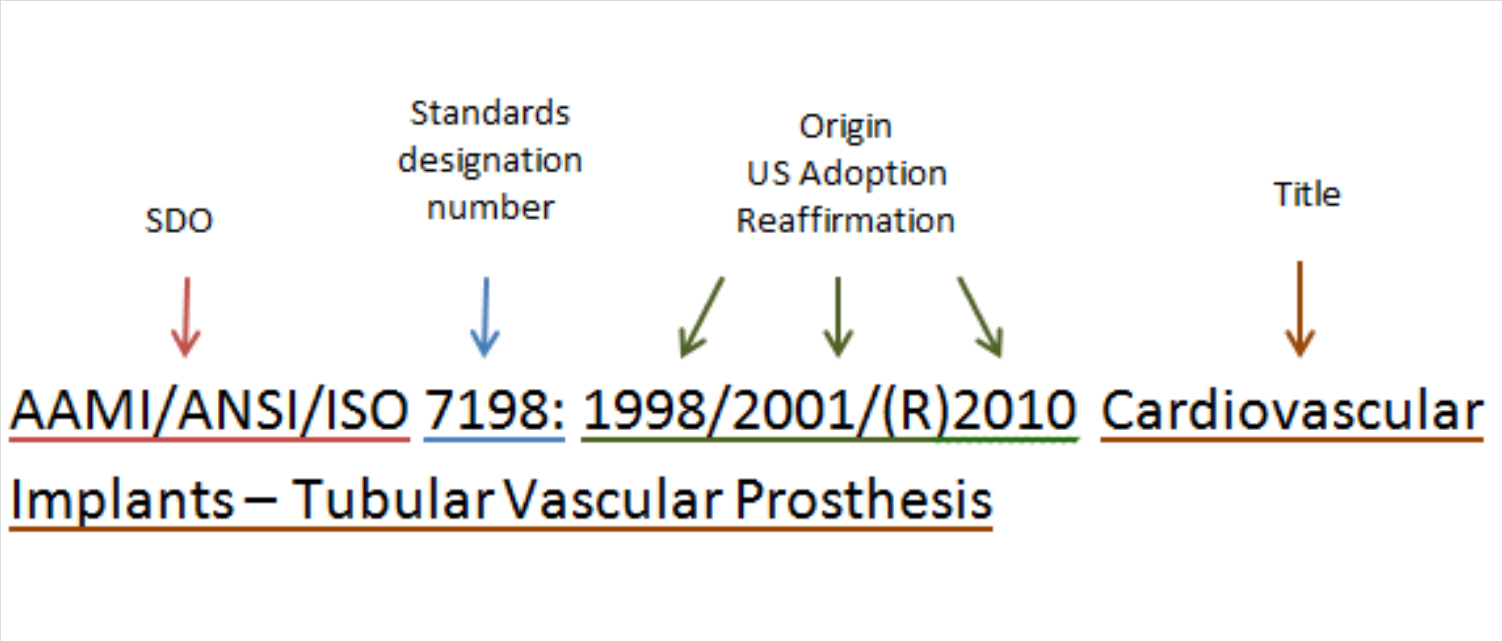
International Standards Title



National Standards Title



U.S. Parallel Adoption



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


FDA
U.S. FOOD & DRUG
ADMINISTRATION