

Standards and Modularity of Brain-Computer Interfaces and Neuroprostheses

Standards at the FDA

June 30, 2016



- 1 - Standards Strategy in the U.S.
- 2 - Standards at the FDA
- 3 - Standards in Neurology

A Standard is...

- Common use of rules, conditions, guidelines for products and production methods...
- A definition of terms; classification, procedures, specification, materials, performance, design, or operations...
- A measurement of quality and quantity in materials, processes, products, systems, services...
- A description or test methods and sampling procedures; measurement of size or strength...

A Voluntary Consensus Standard is...

- A standard developed or adopted by voluntary consensus standards bodies - both national and international.



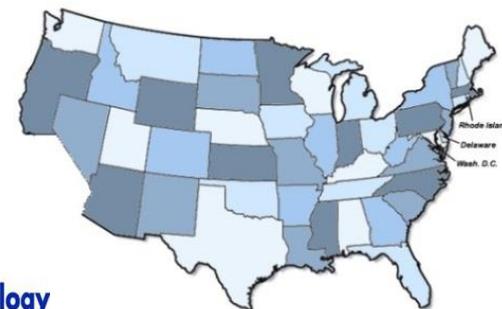
National Standards Strategy

- Congress enacted the NTTAA¹ that established the road map for a market-driven process for setting standards.
- NIST² administers this legislation.
- ANSI³ is the US national body in international standards.

¹National Technology Transfer Agreement Act of 1995 (Law 3/7/96)

²National Institute of Standards & Technology, Gaithersburg, Maryland

³American National Standards Institute, Washington, DC



CDRH-Specific Authorities

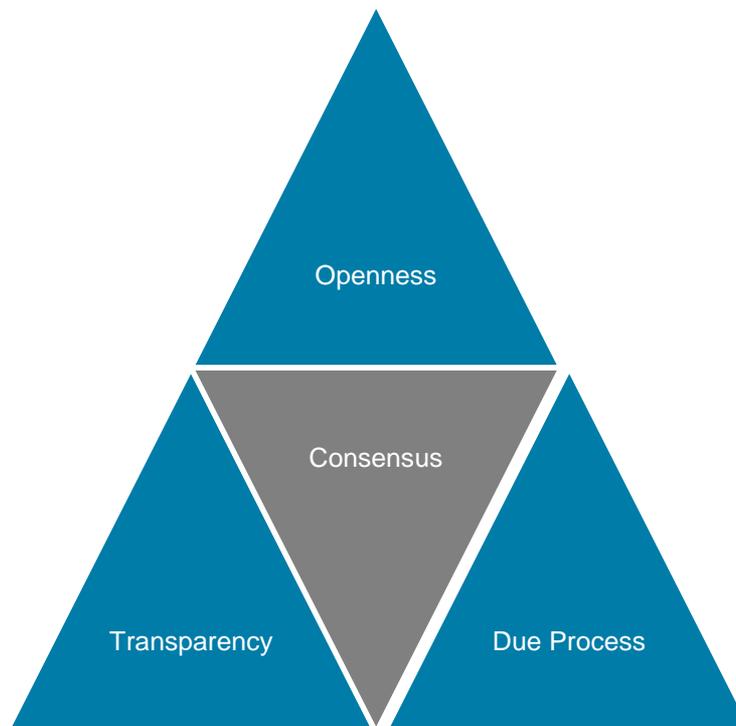
- The current standards program was created as a result of the FDAMA¹.
- This legislation amended Section 514(c) of the Medical Device Amendment of 1976:
 - Allowed FDA to formally recognize consensus standards and to accept a declaration of conformity to a recognized standard.
 - Happy Anniversary – 40 years as of 5/28/2016!



¹Food and Drug Administration Modernization Act of 1997.

Principles of Standards Development

- Openness
- Transparency
- Due Process
- Consensus



Standards Stats

- 700,000 worldwide standards
- 100,000 US standards across all industry sectors
- 1180* FDA-recognized standards
- 600+ working groups by [FDA liaisons](#)



Liaisons serve on Standard Development Organizations (Ex: ODE-DNPMD)



- **AAMI:** Association for the Advancement of Medical Instrumentation is a nonprofit organization founded in 1967. It is a diverse community of nearly 7,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology; <http://www.aami.org/>



- **ASTM:** American Society for Testing and Materials is a leader in the development and delivery of international voluntary consensus standards. Today, some 12,000 ASTM standards are used around the world to improve product quality, enhance safety, facilitate market access and trade, and build consumer confidence; <http://www.astm.org/>



- **IEEE:** IEEE is the Institute of Electrical and Electronics Engineers; <http://www.ieee.org/index.html>



- **ISO:** International Organization for Standardization is the world's largest developer of voluntary International Standards. International Standards give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective; <http://www.iso.org/iso/home.html>



- **RESNA:** Rehabilitation Engineering and Assistive Technology Society of North America. The RESNA Assistive Technology Standards Board is the US TAG to the American National Standards Institute (ANSI) for the development of international standards through the ISO pertaining to assistive technology and other products for persons with disabilities.

Standards at the FDA

- Main Goals
 - Safeguard public health
 - Facilitate the availability of safe and effective products
 - Develop and use product standards
 - Minimize inconsistent standards
- Main Charges
 - Recognize by reference in part or whole
 - Use internationally harmonized standards
 - Reference standards in published guidance documents
 - Encourage sponsors and manufactures to cite standards

Recognition is...

- Statement: FD&C Act - section 514(c)
 - “FDA’s identification of standards as appropriate for manufacturers of medical devices to declare conformance to meet relevant requirements”
 - IOW: Identifying medical device standards that may facilitate the declaration of conformity process
- Means: Publication in the Federal Register
 - Direct recognition – no notice/comment
 - Immediately available
 - Complete/In Part/Non-Recognition

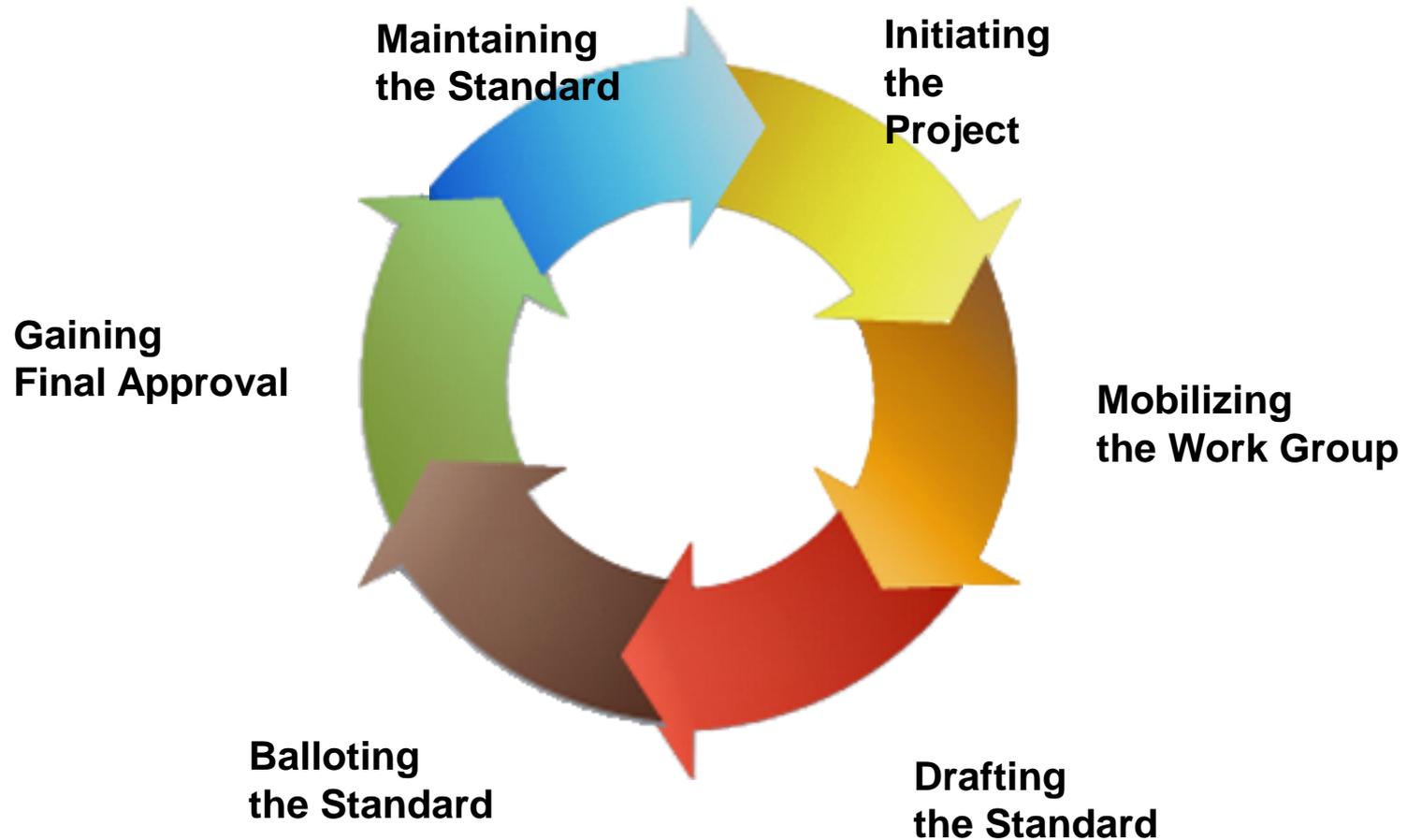
Documentation

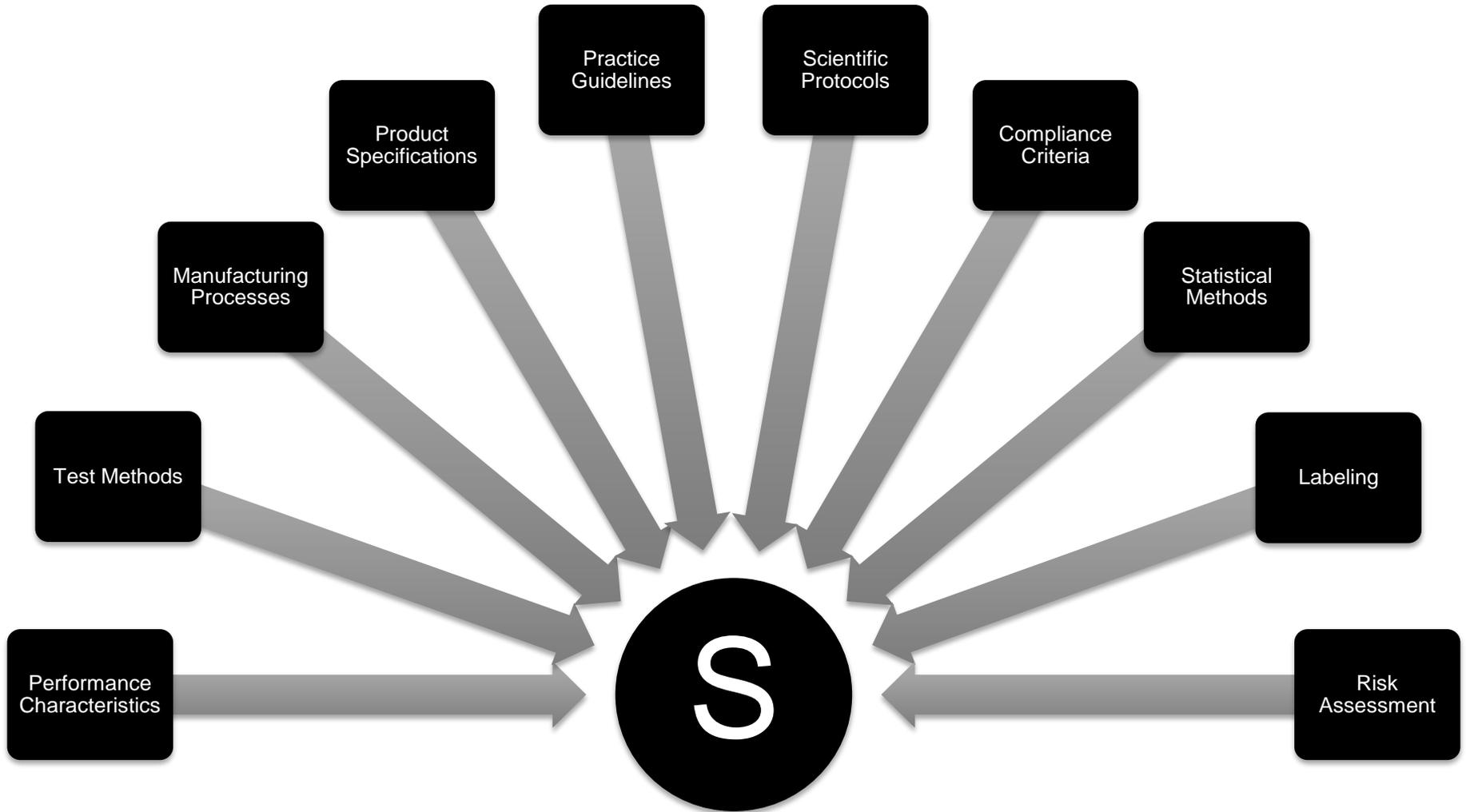
- Declaration of Conformity to an FDA RCS
 - Certification that the device conforms to the requirements of the standard without deviation ([FORM FDA 3654](#))
- Promissory Note
 - Promise to conform to a particular standard
 - Test conditions and acceptance criteria need to be described beforehand

Importance of Standards

- Provides CDRH discretion to use standards in our processes
- Builds consistency, credibility, and predictability
- Assists in the execution of the mission

Standards Development Life Cycle







Draft Standards: Center-wide Circulation

Committee Develops Draft Standard

Committee Members Review the Draft Standard with Stakeholders

FDA Liaisons Send Draft Standard to CDRH SMS Staff

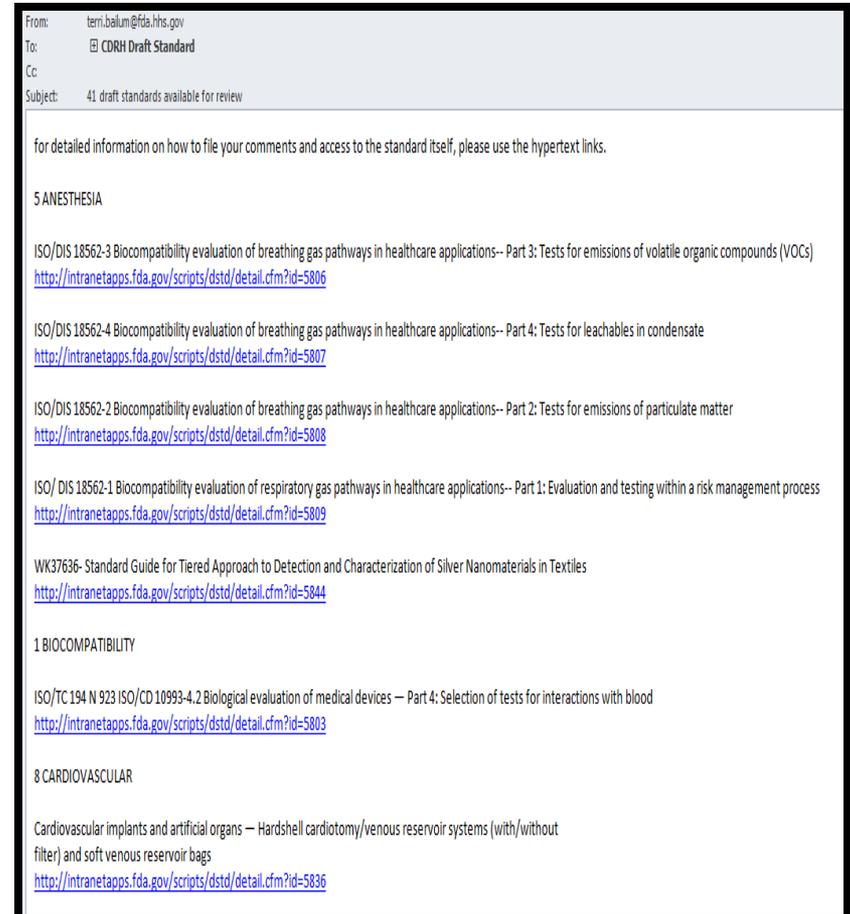
CDRH SMS Staff Circulates Draft Standard to CENTER

Liaison collates comments from ALL submitters; resolves discrepancies

Liaison submits 1 set of comments to Committee and cc's SMS Staff

SMS Staff Updates Draft Standards Database to Track Agency Position

SMS Staff Responds to Inquiry Regarding FDA Votes/Comments



Specialty Task Groups N= 17

- Cardiology
- IVD
- OBGYN-G-U
- **Neurology-Physical Medicine**
- Biocompatibility
- Materials-Tissue Engineering
- Orthopedic
- General I (QS/RM)
- General II (ES/EMC)
- Software/Informatics
- Anesthesia
- General Hospital-General Plastic Surgery
- Sterility
- Dental/ENT
- Ophthalmic
- Radiology
- Nanotechnology



Recognized Consensus Standards

[FDA Home](#)
[Medical Devices](#)
[Databases](#)

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/ucm123792.htm>.
- Please note that changes to the recognized consensus standards database are updated the following Monday.

[Learn More...](#)

Search Database



Standards Organization

All Standards Organizations

Standard Designation Number

Note: numbers only, e.g., 14971, 60601-1

Standards Title or Keywords

Note: do not include standard designation number

(30 chars. max)

Specialty Task Group Area

All Categories



Recognized Consensus Standards



[FDA Home](#)
[Medical Devices](#)
[Databases](#)

1 to 8 of 8 Results

Specialty Task Group Area: *Neurology*

Results per Page

[New Search](#)

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Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
17-8	ISO	14708-3 2008-11-15	Implants For Surgery - Active Implantable Medical Devices Part 3: Implantable Neurostimulators	09/08/2009	Neurology
★ 17-10	AAMI ANSI ISO	14708-3:2008/(R)2011	Implants For Surgery - Active Implantable Medical Devices Part 3: Implantable Neurostimulators	07/09/2014	Neurology
★ 17-11	IEC	60601-2-10 Edition 2.0 2012-06	Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators	08/05/2013	Neurology
17-12	ISO	7197 Third Edition 2006-06-01	Neurosurgical Implants - Sterile, Single-Use Hydrocephalus Shunts And Components [Including: Technical Corrigendum 1 (2007)]	01/30/2014	Neurology
17-4	ASTM	F647-94 (Reapproved 2014)	Standard Practice For Evaluating And Specifying Implantable Shunt Assemblies For Neurosurgical Application	08/14/2015	Neurology
17-1	AAMI	NS28:1988/(R) 2010	Intracranial Pressure Monitoring Devices	01/30/2014	Neurology
17-14	AAMI ANSI	NS4:2013	Transcutaneous Electrical Nerve Stimulators	08/14/2015	Neurology
17-13	IEEE	Std 2010-2012	Recommended Practice For Neurofeedback Systems	01/27/2015	Neurology



Recognized Consensus Standards



FDA Home Medical Devices Databases

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Specialty Task Group Area: *Physical Medicine*

Results per Page 100

New Search

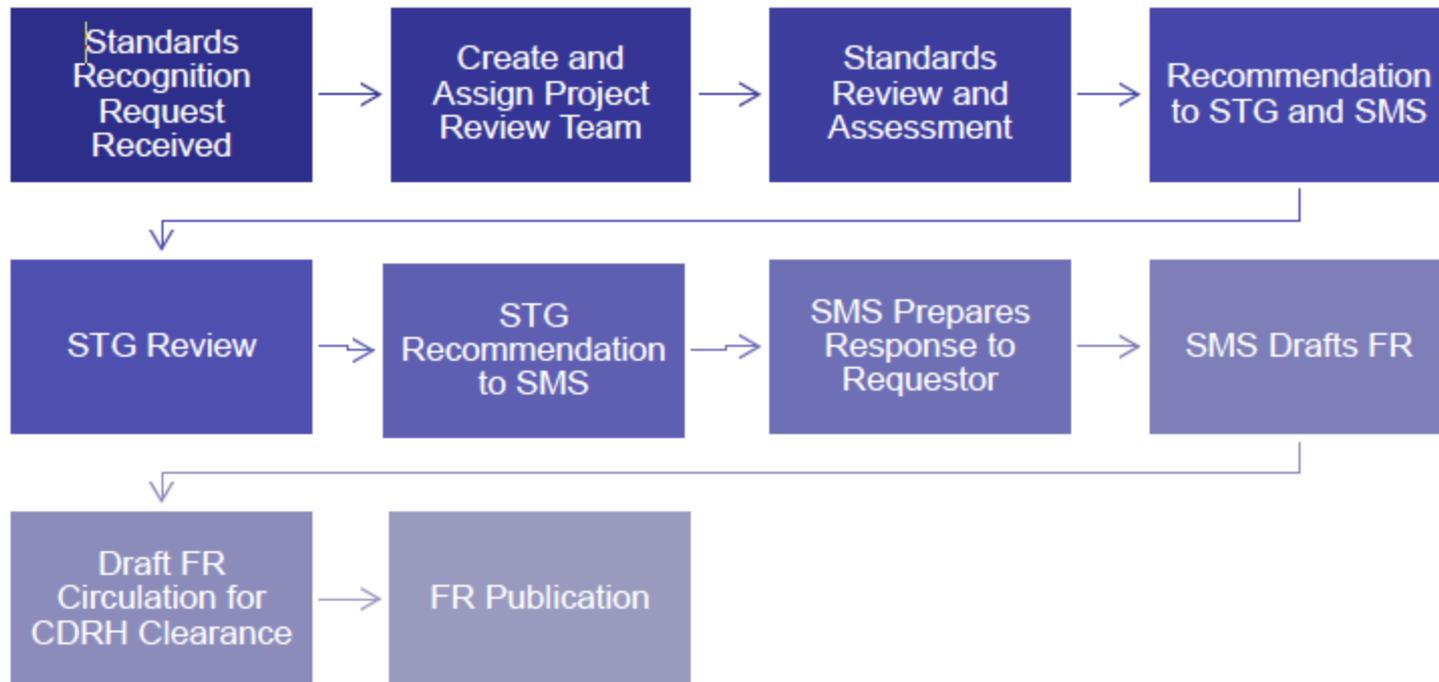
Export To Excel Help

Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	FR Publication Date	Specialty Task Group Area
16-168	ANSI RESNA	WC-1:2009	American National Standard For Wheelchairs - Volume 1: Requirements And Test Methods For Wheelchairs (Including Scooters) Section 1 Determination Of Static Stability	01/30/2014	Physical Medicine
16-25	ISO	7176-13 First Edition 1989-08-01	Wheelchairs - Part 13: Determination Of Coefficient Of Friction Of Test Surfaces	01/30/2014	Physical Medicine
16-27	ISO	7176-15 First Edition 1996-11-15	Wheelchairs - Part 15: Requirements For Information Disclosure, Documentation And Labeling	01/30/2014	Physical Medicine
16-29	ISO	7176-6 Second Edition 2001-10-01	Wheelchairs - Part 6: Determination Of Maximum Speed, Acceleration And Deceleration Of Electric Wheelchairs	01/30/2014	Physical Medicine
16-159	ISO	7176-2 Second Edition 2001-06-15	Wheelchairs - Part 2: Determination Of Dynamic Stability Of Electric Wheelchairs	01/30/2014	Physical Medicine
16-162	ISO	7176-4 Third Edition 2008-10-01	Wheelchairs - Part 4: Energy Consumption Of Electric Wheelchairs And Scooters For Determination Of Theoretical Distance Range	01/30/2014	Physical Medicine
16-163	ISO	7176-5 Second Edition 2008-06-01	Wheelchairs - Part 5: Determination Of Overall Dimensions, Mass And Manoeuvring Space	01/30/2014	Physical Medicine
16-164	ISO	7176-10 Second Edition 2008-11-01	Wheelchairs - Part 10: Determination Of Obstacle-Climbing Ability Of Electrically Powered Wheelchairs	01/30/2014	Physical Medicine

Requests for Recognition

- Stakeholders may propose standards for recognition: CDRHStandardsStaff@fda.hhs.gov
- To make a request, submit
 - Title of the standard
 - Reference number and date
 - Name and address of the standard development org
 - Proposed list of devices or device types
 - Brief discussion of the testing or performance addressed by the standard

Request for Recognition Flow Chart



References

- FDA SMG 9100.1:
 - <http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm193332.htm>
- International Harmonization; Policy on Standards; Notice
 - <http://www.gpo.gov/fdsys/granule/FR-1995-10-11/95-25070>
- National Institutes of Standards and Technology:
 - <http://www.nist.gov/>
- National Technology Transfer and Advancement Act
 - <http://www.nist.gov/standardsgov/nttaa-act.cfm>
- OMB Circular A-119
 - <http://www.nist.gov/standardsgov/omba119.cfm>
- Standards.gov
 - <http://www.nist.gov/standardsgov/index.cfm>

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