CDRH Standards Recognition Process

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Learning Objectives

- Understand how CDRH assesses & recognizes standards
- Identify the different types of recognition
- Find Federal Register documents on standards
- Understand how Organizations maintain Standards
- Learn how to request recognition

CDRH Standards Program

Mission

The CDRH Standards Program was established as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The program contributes to the Center's mission of protecting and promoting public health through the development and recognition of voluntary consensus standards that serve to establish safe and effective medical devices, radiation-emitting products and emerging technologies.

CDRH Standards Program

Vision

CDRH stakeholders have access to high-quality, safe, and effective medical devices of public health importance first in the world through timely development and recognition of voluntary consensus standards. The CDRH Standards Program is the world's leader in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety. Medical Device manufacturers, consumers, patients, and providers have access to voluntary consensus standards for medical devices and use this information to protect and promote the public health.

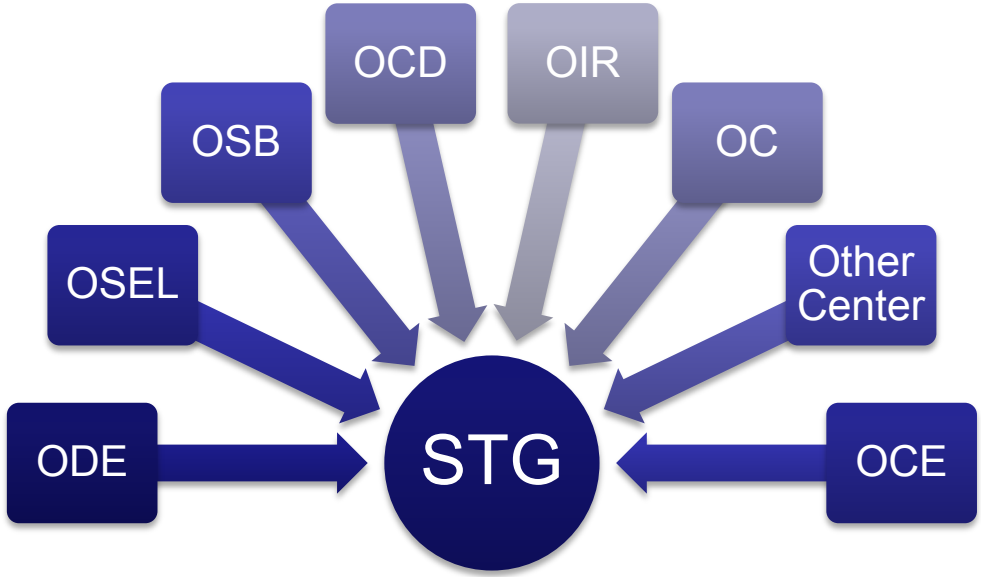
Standards Management Staff

- Standards recognition/priorities
- New/current standards projects
- Travel / Travel priorities
- Standards review/ballot execution
- Liaison representatives
- Membership in SDOs
- License agreements for access to published standards
- Federal Register publications

Specialty Task Groups (STGs)

- Anesthesia
- Biocompatibility
- Cardiovascular
- Dental, ENT
- General I (QS/RM)
- General II (ES/EMC)
- General Hospital/General Plastic Surgery
- *In Vitro* Diagnostics
- Materials
- Nanotechnology
- Neurology
- OB-Gyn/ Gastroenterology/ Urology
- Ophthalmic
- Orthopedic
- Physical Medicine
- Radiology
- Software/Informatics
- Sterility
- Tissue Engineering

Specialty Task Group Representation



STG Duties

- identifies existing and needed standards
- prioritizes standards activities
- coordinates assessment of standard's use to meet regulatory requirement
- recommends recognition of standards
- recommends liaisons, alternates, technical experts
- develops the SIS for recognized standards
- reports to SMS Director

Standards Recognition

"Recognition" defined in Food, Drug, and Cosmetic Act (FD&C) 514(c).

Describes process for FDA identification of standards that manufacturers of medical devices may cite to meet a relevant requirements in the FD&C Act.

Recognizing a Standard

SMS initiates the collection of information on:

- Newly published standards
- Revised standards
- Title changes
- Amendments/corrigenda
- Revised editions
- Withdrawn standards

CDRH Decisions on Standards

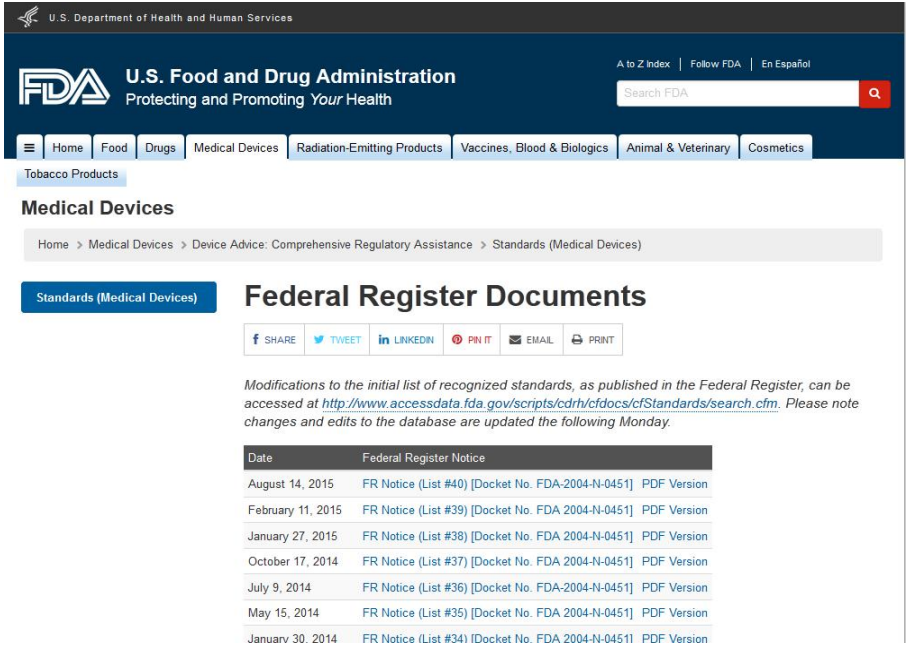
1. Recognition
   - complete/entire standard
2. Recognition in part
   - excluding certain clauses or sections
3. Non-Recognition

* may defer for future assessment

Recognizing a Standard

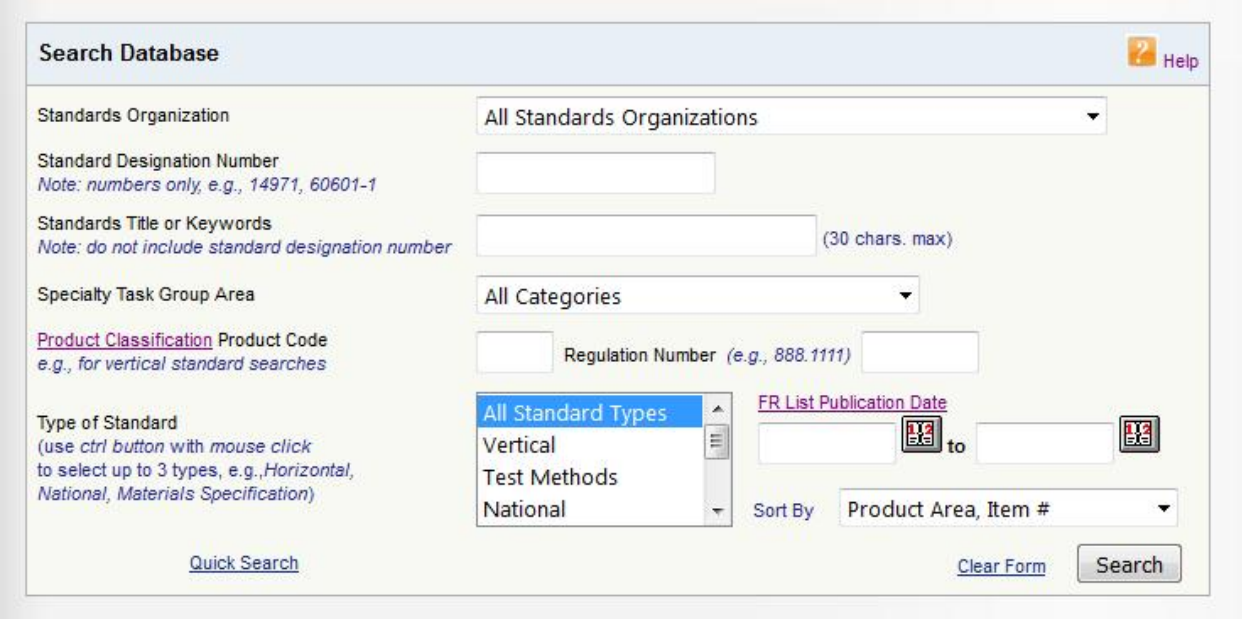
- Federal Register (FR) Notice
- As described in statute, FD&C 514(c)
- Direct recognition – no need for Notice of Availability (NOA) and comments
- Immediately available for use by industry and regulators

Federal Register Documents



http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm

Consensus Standards Database



http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Standards Maintenance

- Standards are typically up for review 3 years after the first publication

- Standards are reviewed for reaffirmation or revision every 5 years after the first 3 year cycle.

Requests for Recognition

- CDRH SOP for the Identification and Evaluation of Candidate Consensus Standards for Recognition

Requests for Recognition

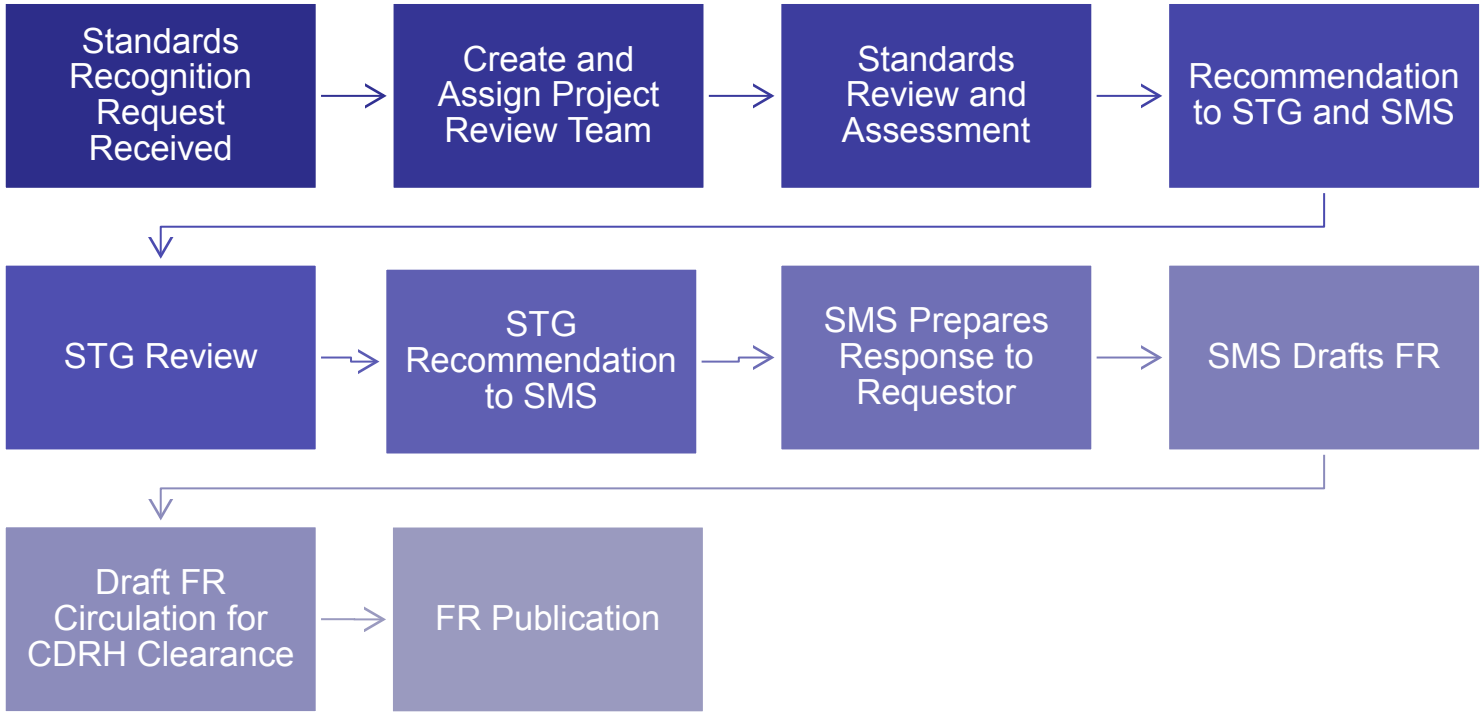
- Stakeholders may propose standards for recognition
- To make a request, submit
  - Title of the standard
  - Any reference number and date
  - Name and address of the SDO
  - A proposed list of devices or device types
  - A brief discussion of the testing or performance or other characteristics that would be addressed by the standard

Requests for Recognition

Requests to CDRH to recognize a standard may be submitted at any time to:

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

Request for Recognition Flow Chart



Summary

1. We learned how CDRH assesses and recognizes standards.
2. We identified the different types of recognition.
3. We learned where FDA lists the Federal Register notices of lists of recognized standards.
4. We learned how different standards organizations maintain standards.
5. We learned how to request the recognition of a standard.