# Standards Overview

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# Learning Objectives

- Define some key terms related to standards
- Review the authorized laws and government organizations involved with standards
- Learn the benefits of why FDA uses standards
- Identify and describe the different types of standards
- Discuss how CDRH uses medical device standards

# Definition of “Standard”

- Also known as "technical standard" per the Food, Drug & Cosmetic Act (FD&C Act)
- Common and repeated use of rules, conditions, guidelines or characteristics
- For products or related processes and production methods, and related management systems practices

# Definition of “Standard” cont:

- definition of terms
- classification or components
- delineation of procedures
- specification or dimensions
- materials
- performance
- design
- operations
- measurements of quality/quantity to describe materials, processes, etc.
- test methods and sampling procedures
- description/measurement of size or strength

# Voluntary Consensus Standard

**Definition**

- a standard developed or adopted by voluntary consensus standards bodies, both domestic and international

**Key attributes include**

- due process, balance of interests, openness, appeals, consensus

# National Technology Transfer and Advancement Act (NTTAA)

- Passed by Congress in 1995
- Signed into law on March 7, 1996
- Grew out of Department of Defense experience

# NTTAA Objective

**Encourage Government Agencies to:**

- Use standards developed/adopted by voluntary consensus bodies
  - ➢ instead of proprietary, non-consensus standards

- Participate in voluntary consensus standards bodies

# References

**National Technology Transfer and Advancement Act**
www.nist.gov/standardsgov/nttaa-act.cfm

**Standards.gov**
www.nist.gov/standardsgov/index.cfm

# OMB Circular A-119

# OMB Circular A-119

- **OMB** = Office of Management and Budget
- **OMB establishes policies on:**
  - Federal use and development of voluntary consensus standards
  - Conformity assessment activities
  - Defined commonly-used terms

# OMB Circular A-119

- Establishes requirements for Agency participation
- Describes reporting requirements
- Describes requirements for incorporating standards into Agency regulations
  - FDA use of standards is voluntary, unless in regulation

# OMB Circular A-119 Goals

- Eliminate government costs
- Provide incentives that serve national needs
- Encourage long-term growth for the US
- Promote economic competition

# Role of NIST

- NIST = National Institute of Standards and Technology
- Works with US industry, standards developers, and other government agencies to build a standards infrastructure
- Monitors and participates in standards development and conformity assessment

# References

**OMB Circular A-119**

https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf

**National Institutes of Standards and Technology**

www.nist.gov

# FDA Use of Standards

- **21 Code of Federal Regulation (CFR) 10.95:**
  - Participation in outside standard-setting activities
- **FDA Policy**
  - addresses development and use of standards with respect to international harmonization of regulatory requirements and guidelines
  - 60 FR 53078 (Oct. 11, 1995)
- **FDA Staff Manual Guide 9100.1**
  - adopted March 2007

# International Harmonization of Standards

**FDA Goals**

1. Assure that consumer protection standards and requirements are met
2. Facilitate availability of safe and effective products
3. Develop and use product standards
4. Minimize/eliminate inconsistent standards internationally

# FDA Staff Manual Guide

- Outlines policies/procedures to assure unified approach to standards
- Details responsibilities
- Describes establishment of agency-wide standards program

# FDA Staff Manual Guide

- Preferentially use international harmonized standards
- Reference standards in guidances, where appropriate
- Encourage submitters of medical device applications to cite standards
- Incorporate consensus standards

# References

**International Harmonization; Policy on Standards; Notice**
www.gpo.gov/fdsys/granule/FR-1995-10-11/95-25070

**FDA SMG 9100.1**

www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm193332.htm

# Standards in FDA Law

# FDA Modernization Act of 1997

- Revised Section 514(c)
- Added ability to formally recognize a standard, “all or in part”
- Added ability to accept a formal Declaration of Conformity

# Recognition of a Standard

- Identification of a standard to meet a requirement
- May apply to a new standard or a new version of an existing standard
- Recognitions posted for the public

# 21st Century Cures Act of 2016

- Revised Section 514(c)
- Added timeframe for public request for FDA to recognize a standard
- Required FDA to respond to the requester
- Required FDA to publish basis for decision
  - i.e., recognition of all, part, or none of a standard

# 21st Century Cures Act of 2016

- Required FDA staff to be trained on the use of standards
- Required FDA to develop a guidance document about standards recognition process

# Standards Recognition

"by **publication in the FR, recognize all or part** of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person **may submit a declaration of conformity** in order to meet a premarket requirement or other applicable requirement under this chapter to which such standard is applicable"

**Section 514(c)(1)(A)**

# Standards Recognition - cont

- If a person **elects** to use a standard, then they shall **provide a declaration of conformity** to that standard

- A person may elect to use data, or information other than data required by a standard, to meet any device requirement

**Section 514(c)(1)(B)**

# Standards Recognition - cont

- Notify requester of recognition request
- Make determination of extent of recognition
- Notify requester of decision and rationale
- Implement standard

**Section 514(c)(1)(C)(ii-iv)**

# Standards Recognition - cont

- FDA will make non-recognition decisions publicly available.
- FDA may withdraw recognition when a standard is no longer appropriate.

**Section 514(c)(1)(D)**

# Declaration of Conformity

- Applies to FDA-recognized standards
- May not deviate from the FDA-recognized standard
- Is a certification that a device conforms to the requirements identified in an FDA-recognized standard

**Section 514(c)(1)(A)**

# Declaration of Conformity

FDA shall accept declaration of conformity unless:

1. data/information do not demonstrate that device conforms with standard; or
2. identified standard is not applicable

**Section 514(c)(3)(A)**

# Importance of Standards

- Give CDRH discretion to use standards in any process
- Build consistency, credibility, and predictability
- Are integral in execution of CDRH mission:
  - Performance characteristics
  - Testing methods
  - Manufacturing practices

# Types of Standards

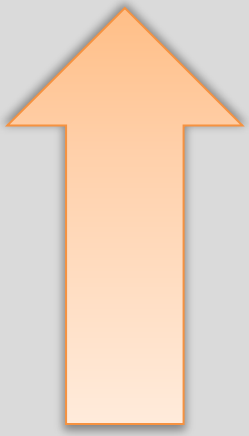
- Vertical
- Test Methods
- National
- Horizontal
- Material Specifications
- International

# Vertical

- Apply to specific devices or device groupings
- Prescribes specific procedures to evaluate these aspects
- CDRH has recognized several hundred of this type of standard

**Example:**

ANSI/AAMI/IEC 60601-2-25 Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs



# Horizontal

- Apply across a wide ranges of devices and device types
- Built in flexibility: used across a range products or processes
- General principles and guidelines are laid out,  but details are left up to the user
- Apply when a condition is not covered by a vertical standard
- CDRH has recognized several hundred horizontal standards

# Sterilization

Example:

ISO 11135 Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation, and routine monitoring of a sterilization process for medical devices.

# Test Methods

- Definitive procedure that produces a test result
- Test result may be used to assess compliance with a standard specification
- CDRH has recognized approximately 100 test methods

## Procedure

1 → 2 → 3

**Example:**

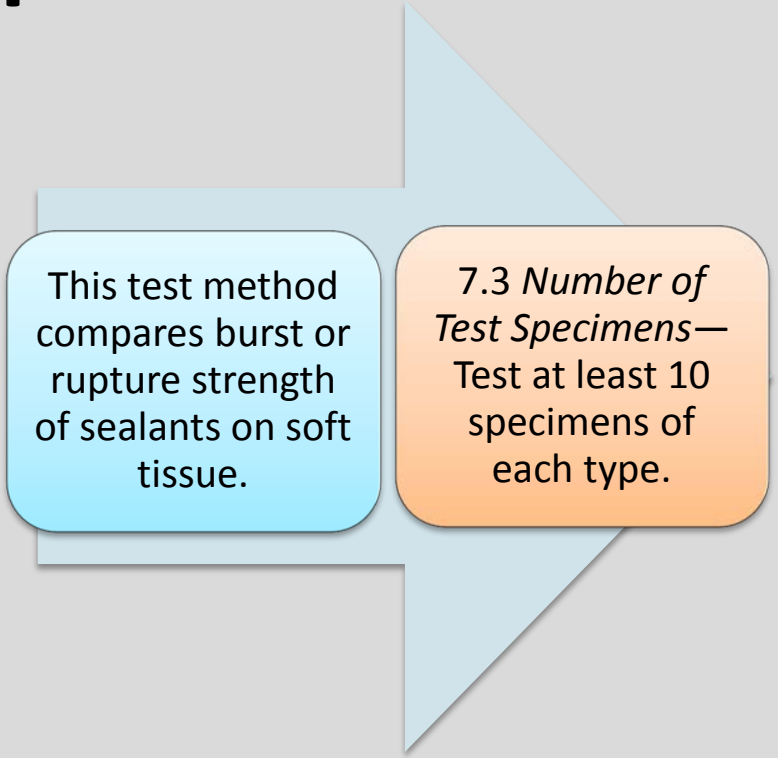
CLSI M43-A Methods For Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline

# Material Specification

- Typically includes requirements for physical, mechanical, or chemical properties, and safety, quality or performance criteria.
- Explicit set of requirements to be satisfied by a material, product, system or service.

**Example:**

ASTM F2392-04(Reapproved 2015) Standard Test Method For Burst Strength of Surgical Sealants



# National

- Produced by US standards developing organizations
- Designated as an “ANS” or American National Standard
- Accredited through American National Standards Institute (ANSI)
- Example: ANSI/AAMI ES60601-1

# International

- Developed by a harmonized international standards developing organization
- Examples:
  - International Organization for Standardization (ISO)
  - International Electrotechnical Commission (IEC)
  - ASTM International
  - IEEE
  - Underwriters Laboratory (UL)

# US Adoption of International Standards

International standard that is adopted:

- in parallel with the international SDO; or
- with changes or deviations

# Other Standards Products

**Standard Practice -** Defines a sequence of operations, that unlike a Test Method, does not produce a result. Examples: selection, preparation, application, etc.

**Guide -** An organized collection of information or series of options that does not recommend a specific course of action

**Practice Guideline -** A set of instructions for performing one or more specific operations that does not produce a test result.

# Where Standards May be Used

- Clinical Issue
- Labeling
- Symbol
- Device Identifier
- Pre-Market
- Post-Market
- Radiological Health
- Public Health Concern

- Informed Consent, Study Subject Protection
- Manufacturing
- Quality Systems Regulation
- Risk Management/Assessment
- Human Factors
- Good Laboratory Practices

# Use in Premarket Submissions

- **Used in a variety of premarket submissions**
  - Premarket Notification (510(k) – Traditional, Abbreviated and Special)
  - De Novo
  - Premarket Approval (PMA)
  - Humanitarian Device Exemption (HDE)
  - Investigational Device Exemption (IDE)
  - Pre-Submission
  - Applicable CBER biological submission

# Summary

1. We learned the definition of a standard and its different types
2. We reviewed the key pieces of legislation that formed the basis of the U.S. National Standards Strategy
3. We discussed the evolution of standards as used by FDA
4. We reviewed how standards are used by FDA and for what types of submissions they may be used

# 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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