



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION



# Use of Voluntary Consensus Standards by a Regulatory Agency

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# Standards 101

“ The needs of business drive standards”

Hon William M. Daley, US Secretary of Commerce

# Regulatory Forces in the US

## Device Authorities

FDA, FTC

## Hospital & Clinical Laboratory

FDA, HCFA, CLIA, MQSA, JCAHCO

## Trade Authorities

FTC, WTO

## Others

FCC (wireless, telemetry)

NRC (nuclear radiation)

# Product Areas Relevant to WSC Workshop

- Center for Biologics
  - Blood delivery products
- Center for Devices and Radiological Health
  - Medical devices, including in-vitro diagnostic products
  - Electronic products that emit radiation
- Center for Drug Evaluation and Research
  - Drug delivery products

# Regulation = Risk Management



- Is the product safe to use
- Is the product effective – Does it do what it claims to do
- Risk vs. Benefit – The eternal question

# Regulatory Authorities

- Authorities provided by Congress
  - Medical Device Amendments of 1976
  - Safe Medical Device Act of 1990
  - Technology Transfer Act of 1996
  - Food and Drug Modernization Act of 1997
- Authorities provided by the President
  - OMB A119 (1982) (1993)

# Participation = Leveraging

- More than 220 staff participate in more than 500 committees developing medical technology product standards

# Accomplishments by FDA's Medical Device Standards Program



- >600 voluntary consensus medical technology standards “recognized” on 8 published lists
- Cited in thousands of 510(k)s and PMAs
- Staff Professional Development

# Conformity Assessment

- A regulatory process - cannot be delegated
- Consensus standards are a building block to enable harmonization

# Use of consensus standards by Regulators

- Standards are valued only as used by Stakeholders
- Use of consensus standards is voluntary
- There are multiple sources of acceptable standards
- Standards should cite the best technology
- Parallel development of similar standards is wasteful

# Useful Internet Websites



- <http://www.cdrh.fda.gov/SCIENCE/STANDARDS/constand.htm>
- <http://www.fda.gov>