

# Role of Standards in the Assessment of Medical Devices



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IVD. 2008





- Background on CDRH Standards
- Standards Management in CDRH
- Recognizing a Standard
- Guidance
- Future



# BACKGROUND

## Use of Consensus Standards by Federal Agencies

- Codified in PL 104-113 National Technology Transfer and Advancement Act of 1995
- Interpreted by OMB Circular A119-1997 (currently being revised)
- Implemented by NIST
- Standards and Global Harmonization



## BACKGROUND (cont.)

### Food & Drug Administration Modernization Act (FDAMA)

- Section 514 (21 U.S.C. 360d) is amended by adding:

...by publication in the Federal Register, 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 submission requirement or other requirement under this Act to which such standard is applicable.



## BACKGROUND (cont.)

### Why Use FDA Recognized Consensus Standards?

- Facilitates the premarket review process
- Conformance with Recognized Consensus Standards can provide reasonable assurance of safety and effectiveness for many aspects of medical device evaluation.
- Standards produce voluntary consensus among industry, health care device users and FDA.
- Standards are updated as technology and experience advance



# BACKGROUND (cont.)

## Standards Recognition Activities

- 2/25/98 — recognized 174 standards
- Approximately 100 standards under evaluation at any time
- Have recognized over 900 standards to date
- Participating in over 500 current committees
  - changes as committees sunset
  - changes as new committees get formed
- Approximately 250 staff
- Ensuring a seat at the table



# BACKGROUND (cont.)

## Standardization (cont.)

- Is based on consolidated results of science, technique, and experience. Some particular applications are:
  - units of measure;
  - terminology and symbols;
  - products and processes; and
  - safety of persons and goods



# Standards Management (cont.)

## Specialty Task Groups (STGs)

- Anesthesia
- Biocompatibility
- Cardiology/Neurology
- Dental/ENT
- General
- General Hospital/ General Plastic Surgery
- **IVDs**
- Materials
- OB-BYN/Gastroenterology
- Ophthalmic
- Orthopedics/Physical Medicine
- Radiology
- Software
- Sterility
- Tissue Engineering



# Standards Management (cont.)

## Specialty Task Groups (STGs) responsibilities

- STGs annually review standards priorities and establish the priority score, according to common criteria for each proposed and on-going standards development effort.
- STGs recommend appointment of the liaisons to Standards Development Committees, however the Standards Director makes appointment
- STGs review and recommend standards for recognition by CDRH.
- STGs periodically review previously recognized Standards to assure validity with current science and the public health.



# Standards Management in CDRH

- Liaison Vacancy
- Liaison Representative
- Travel / Travel Priorities
- Document Review



# Standards Management (cont.)

## Liaison Vacancies

- Liaison Rep Vacancies (SOPs)
  - CDRH wide announcement
  - Nominations to STG Coordinator - must have supervisory concurrence
  - STG makes recommendation to SPCS Director
  - Letter to SDOs
  - No liaison privileges if process not followed (cv, information sheet)



# Standards Management (cont.)

## Liaison Representative Responsibilities

- Standards Review
  - Forward to Standards Coordinator
  - Emailed to CDRH weekly
  - Coordinate responses
- Balloting
  - Notify Coordinator of receipt of ballot
  - Get ballot to Coordinator before deadline



# Standards Management (cont.)

## Trip Reports

- When?
  - SMS wants within 30 days of meeting
  - OC/International Relations Staff wants in 10 days
- What are the possible consequences?
  - Next trip denied
  - Liaison Rep replacement



## Standards Management (cont.)



### Document Review


- Review documents circulated throughout CDRH
- Comments compiled
- Center/Agency representation in discussion and vote
- Published standard is vetted again to determine “extent of recognition”  
(STG responsible for this function)



# CDRH Consensus Standards Activity Management (CSAM) Database

Go to site

committeeist.cfm





U.S. Food and Drug Administration  
**Center for Devices and Radiological Health**

## Consensus Standards Activity Management

[Go To Administrator's Site \(password required\)](#)

Records Found: 2.

ORG ▲ ▼	COMMITTEE ▲ ▼	SUB-COMMITTEE ▲ ▼	WORKING GROUP ▲ ▼	SUB-WORKING GROUP ▲ ▼	STG ▲ ▼	PR ▲ ▼	MEMBER
CLSI 	Area Committee on Hematology				IVD	13	<b>PRIMARY:</b> JOSEPHINE M BAUTISTA, (CDRH, OIVD) <b>ALTERNATE:</b> LARRY J BRINDZA, (CDRH, OIVD)
CLSI 	Area Committee on Hematology	Subcommittee on Coagulation Testing			IVD	13	<b>PRIMARY:</b> LARRY J BRINDZA, (CDRH, OIVD) <b>ALTERNATE:</b> GINETTE Y MICHAUD, (CDRH, OIVD)



# Nationally or internationally recognized standard development organization

- Voluntary consensus process
- Criteria include:
  - Openness
  - Balance of interest
  - Due process
  - An appeals process
  - Consensus



# Recognition Process

- Participate on appropriate standards committees
- Continue the open, transparent process throughout CDRH
- Determine “extend of recognition”
- Publish in Federal Register



# Recognition Process

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## What is needed to recognize a standard

- Supplemental Information Sheet (SIS)
- Details of each recognition
- Products, processes, regulations, codes, contact
- Extent of Recognition identifies limitations, additions, etc.



# Recognition Process - **SAMPLE SISs**

- Item 7-159: CLSI H21-A5, Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays. (InVitro Diagnostics)
- Date of Standard: 2008.
- **Address of Standards Organization:**
  - CLINICAL LABORATORY STANDARDS INSTITUTE (CLSI)
  - 940 WEST VALLEY ROAD
  - SUITE 1400
  - WAYNE, PA 19087
  -
- **CDRH Offices and Divisions Associated with Recognized Standards:**
  - (1) OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (OIVD)
  - DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES (DCTD)
  - 
  - (2) OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (OIVD)
  - DIVISION OF IMMUNOLOGY AND HEMATOLOGY DEVICES (DIHD)
  - 
  - (3) OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (OIVD)
  - DIVISION OF MICROBIOLOGY DEVICES (DMD)



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# Recognition Process -SISs (cont.)

- **Devices Affected:**
  - Hematology devices using blood specimens for coagulation testing.
  -
- **Processes Affected:**
  - 510(k), PMA, PDP, IDE, HDE
  - 
  - Type of Standard:
    - International
  - Extent of Recognition:
    - Complete standard
  -
- **Related CFR Citations and Product Codes:**
  - 
  - Regulation
  - Number Device Name Device
  - Class Product
  - Code
  - §864.5400 Instrument, Coagulation, Automated Class 2 GKP
  - §864.5400 Timer, Clot, Automated Class 2 GKN
  - §864.5400 Timer, Coagulation Class 2 JBT
  - §876.1500 Endoscope And/Or Accessories Class 2 KOG



# Recognition Process – SIS (cont.)

- CFR §864.5400
- Regulation
- Number Device Name Device
- Class Product
- Code
- §864.5400 Fibrometer Class 2 GIE
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- **Relevant Guidance:**
- NCCLS:
- C28-A2 - How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition (2000)
- H1-A5 - Tubes and Additives for Venous Blood Specimen Collection; Approved Standard - Fifth Edition (2003)
- H3-A5 - Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Fifth Edition (2003)
- H47-A - One Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT Test); - Approved Guideline (1996)
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- **FDA Technical Contact:**
- Valerie R. Ginyard
- FDA/CDRH/OIVD/DIHD
- 2094 GAITHER ROAD, HFZ-440
- ROCKVILLE MD 20850
- 240/276-0992
- Email: [valerie.ginyard@fda.hhs.gov](mailto:valerie.ginyard@fda.hhs.gov)



# Standards Guidances



- Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff
- Opportunity to Recommend Standards for CDRH Recognition
- Frequently Asked Questions on the Recognition of Consensus Standards; Guidance for Industry and for FDA Staff
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition; Final Guidance for Industry
- <http://www.fda.gov/cdrh/stdsprog.html>



## Now and tomorrow...

- Need harmonized standards
- Need standards bodies to be more global in products and approach
- Need the GHTF (Global Harmonization Task Force) and regulatory authorities to continue to cooperate and bridge differences

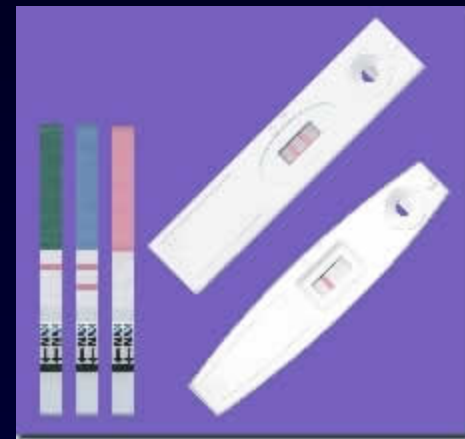


# Thank You!

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Questions?

