CDRH Standards Update
Topics

• CDRH’s Current Activities with Standards

• Recent Standards Guidance Documents

• ASCA

• IMDRF
Streamlining Regulatory Processes

• Improved standards use and recognition
  – Final guidance: Appropriate Use of Voluntary Consensus Standards (VCS)
  – Draft guidance: Recognition & Withdrawal of VCS
  – Redesigned Recognition Database to improve selection and use of VCS

• Accreditation Scheme for Conformity Assessment [ASCA] pilot program
  – Enhancing regulatory efficiencies with increased consistency in FDA’s approach to assessing conformance to standards

• Regulatory reduction efforts
  – Forthcoming guidance: Medical X-ray Imaging Devices Conformance with IEC standards
  – Transition to ISO 13485: Medical devices - Quality management systems -- Requirements for regulatory purposes
Contains Nonbinding Recommendations

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 14, 2018.
2018 Final Guidance: Changes from Draft to Final

- Incorporation of 21st Century Cures Act
- Clarification of Section 514(c) about when deviations are made and the use of promissory statements
- Clarification of the use of standards with or without a DOC
- Adoption of ISO/IEC 17050-1 Conformity assessment – Supplier’s declaration of conformity
- Adoption of ISO/IEC 17050-2 Conformity assessment – Supplier’s declaration of conformity – Supporting documentation
  - Clarification of when and how much supporting information should be provided
- Inclusion of a transition period for all standards that are withdrawn and replaced with a newer version
- Form 3654 no longer needed
21st Century Cures

1. Clarified outside requests for recognition

2. Added:
   • 60-day timeframe
   • Basis for recognition, all or part
   • Basis for non-recognition
   • Training for all reviewers of premarket submissions
   • Periodic training on standards
Declaration of Conformity (DOC)

What does this mean?

– All normative requirements of the standard are met and testing conducted before premarket submission

– Testing is on the finished device or final finished device
Supporting Documentation

Supporting documentation *accompanies* a DOC when:

- The standard describes a test method or procedure with NO acceptance criteria
- The standard includes acceptance criteria but NO test method
- The standard includes choices:
  - What is tested
  - How it is tested (method)
  - Describes a process, e.g., risk assessment, etc.
Contains Nonbinding Recommendations

Draft – Not for Implementation

Recognition and Withdrawal of Voluntary Consensus Standards

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance is being distributed for comment purposes only.

Document issued on September 14, 2018.
Recognition and Withdrawal Guidance

• Describes the recognition process
• Recognition of national standards of other countries when Intl. or USA standard not available
• Request of Recognition
• Extent of Recognition
• Non-Recognition & Notification of Decision
• CDRH Supplemental Information Sheets
Requests for FDA Recognition of Standards

• Any interested party may request recognition of a standard:
  • CDRHStandardsStaff@fda.hhs.gov
    • Name & email (or mailing) address of the requestor,
    • Title of the standard,
    • Any reference number and date,
    • Proposed list of device types for which a declaration of conformity would apply,
    • *Basis for recognition, e.g., including the scientific, technical, regulatory, or other basis for such request,*
    • *a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.*
    • *Typically do not need to provide a copy of the standard.*
FDA Action on Recognition Requests

• Once submitted, FDA’s goal is to respond to the requestor within 60 days with a recognition decision of all or part of the standard, including:
  – Basis for recognition
  – Basis for non-recognition of certain clauses or section

• Or, for a non-recognition decision, the basis for the decision
Notification

• The requestor is notified via official letter

• For recognitions, all or part:
  – Recognized Standards Database is updated with Supplementary Information
  – Notice in the Federal Register

• For Non-Recognitions
  – Non-Recognized Standards Webpage is updated

• Decision based on:
  – Regulatory, Scientific, Technical
Supplementary Information Sheet

A supplementary information sheet after selecting one of the standards.

NOTE: TIRs are cited under “Relevant Guidance and Supportive Publications”
Standards - the Future

• Streamlining regulatory processes
  – Improved standards use and recognition (21st Century Cures)
  – ASCA – Accreditation Scheme for Conformity Assessment (MDUFA IV)
  – Regulatory reduction efforts

• Global commitments - IMDRF
  – Enhanced reliance upon consensus standards
  – Harmonization among global regulators on common use of standards
  – Medical Device Single Review Program
ASCA Pilot – Relationships

**Accredits** Testing Labs according to ISO/IEC 17025 and FDA specific requirements

**Conducts** testing and produces test reports of specific product characteristics per defined test method

Manufacturer **contracts** with testing lab for testing report to submit to FDA

FDA
- Defines and oversees pilot
- Establishes additional specific program requirements to clarify ISO/IEC conformity assessment standards
- Specifies rules and procedures for approval at all levels of the program

**Accreditation Body**
- ISO/IEC 17011 + FDA requirements

**Testing Laboratory**
- ISO/IEC 17025 + FDA requirements

**Medical Device Product Characteristics**
- Basic Safety and Essential Performance
- Biocompatibility
Stakeholders - Pre-ASCA

Accreditation Bodies

FDA

Testing Labs

MFRs

Review Interaction
Submission with DoC

Device Sample Test Reports
ASCA Pilot: A Community of Stakeholders

Accreditation Bodies

Testing Labs

FDA

MFR

ASCA Accreditation

ASCA Recognition

Inquiry

Submission with DoC

Review

Interaction

Device Sample

Test Reports
Why ASCA?

• Conformity assessment is a key element of successful expansion of standards in regulatory review
• Making standards ‘performance based’ and building practicable conformity assessment expectations into standards will:
  – Reduce burden on manufacturers and reviewers
  – Harmonize regulatory processes internally and around the world
• An important vehicle to bring ABs, TLs, manufacturers and FDA together to:
  – Enhance communications
  – Identify improvements in conformity assessment approaches
  – Drive technology into the market quicker
• Forum established in 2011 to accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force (GHTF)

• Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies

• Accelerate innovation by clear and practical regulatory expectations
Global Commitments:

• Enhanced reliance upon consensus standards
  – More and better regulatory-ready standards
  – Increased regulatory authority participation in standards development at the national and international level
  – IMDRF Guidance: *Optimizing Standards for Regulatory Purposes*

• Harmonization among global regulators
  – Research into policy differences on how standards are recognized and used will provide basis for enhanced harmonization

• Medical Device Single Review Program (MDSRP)
  – Single regulatory premarket review to satisfy the needs of multiple regulatory jurisdictions
Standards Web Resources

National Institute of Standards and Technology:
https://www.nist.gov/standardsgov

CDRH Standards and Conformity Assessment Program:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

FDA Recognized Standards Database:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Device Advice - Comprehensive Regulatory Assistance:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

CDRH Learn:
https://www.fda.gov/Training/CDRHLearn/default.htm

International Medical Device Regulators Forum:
http://imdrf.org/

International Organization for Standardization (ISO)
https://www.iso.org/home.html

International Electrotechnical Commission (IEC)
http://www.iec.ch/
THANK YOU!

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