FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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

Scott Colburn
Director
Standards & Conformity Assessment Program
Office of the Center Director
Center for Devices and Radiological Health

Agenda

- Final guidance
- Declaration of Conformity
- General Use
- FDA Review of Declaration of Conformity
- Supplementary Information versus Supporting Documentation
- Questions and Answers

Take Home Messages from Stakeholders

- Least burdensome approach
- Consistency about data requests and test reports
- Transparency about how horizontal standards are applied
- Reduce paperwork, Form 3654 in particular

Objectives

For any type of submission:

- Elect whether to provide a Declaration of Conformity or General Use
- What to provide if the submitter elects a Declaration of Conformity
- What to provide if the submitter elects General Use
- Determine when supporting documentation should accompany the Declaration of Conformity and when it should not.

Guidance

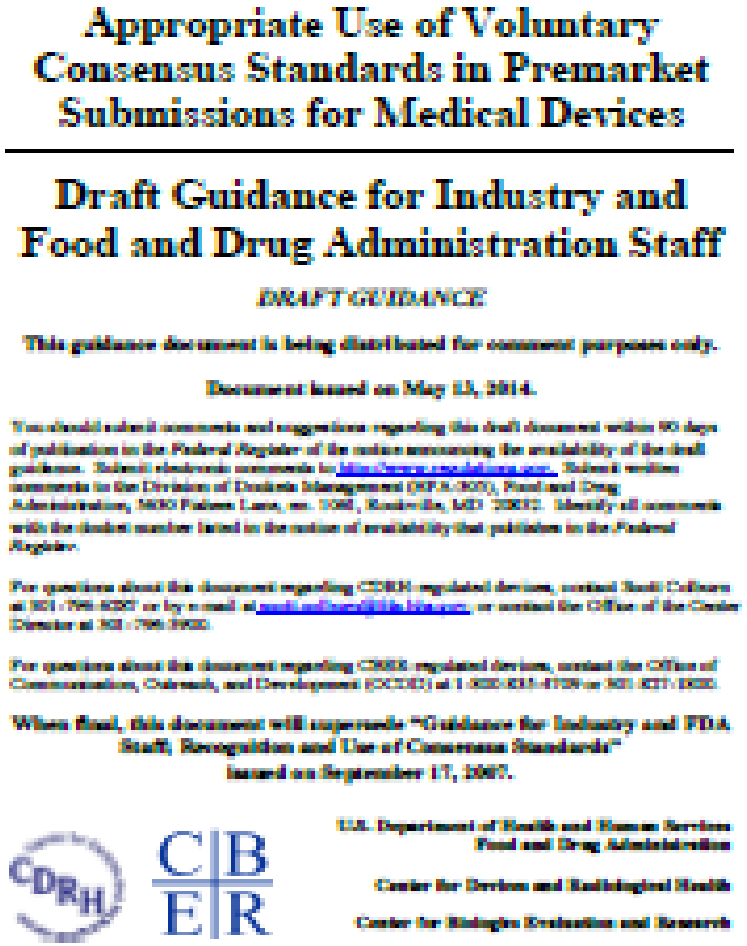
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

2014: Draft Guidance

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

Scope:

- Describes use and documentation of FDA-recognized and non-recognized consensus standards for premarket submissions
- Discussed how FDA staff intends to rely on consensus standards during the review process.
- Clarified and explained regulatory framework, policies, and practices
- Does not:
  - address the specific content required in any particular premarket submission.
  - consensus standards that are incorporated by reference (IBR) into regulation (e.g., hearing aid devices, professional and patient labeling, 21 CFR 801.420(c)(4)).
  - For additional information, see the Standards Incorporated by Reference Database.



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

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on May 13, 2014.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions about this document regarding CDRH-regulated devices, contact Heidi Cullhane at 301-796-6200 or by e-mail at heidi.cullhane@fda.hhs.gov, or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 301-827-1800.

When final, this document will supersede "Guidance for Industry and FDA Staff, Recognition and Use of Consensus Standards" issued on September 17, 2007.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Comments on the Draft

Comments Fell Into Four Categories

- The two policy changes related to the non-acceptance of Declaration of Conformity & promissory statements
- Deviations
- Form 3654
- Transition periods

2018 Final Guidance: Changes from Draft to Final

- Incorporation of changes to Section 514(c) amended by 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 Declaration of Conformity
- 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 Act

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 is a Declaration of Conformity?

- Attestation that the device is in conformity

- If submitter declares conformity, a Declaration of Conformity must be included in the submission

- Reduces the amount of supporting data and information submitted to FDA

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

What is a Finished Device

Under 21 CFR 820.3(l), A Finished Device is:

“Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.”

A Final Finished Device is:

Any device that includes all manufacturing processes for the “to be marketed” device, including packaging and sterilization, if applicable.

ISO/IEC 17050-1 Declaration of Conformity (DOC) Elements

1. Name and address of applicant/sponsor
2. Product/device identification
3. Statement of conformity (not compliance)
4. List of standards applicable including options selected
5. FDA recognition number for each standard
6. Date and place of issuance of the Declaration of Conformity
7. Signature, printed name
8. Any limitation on the Declaration of Conformity

Example of a Declaration of Conformity

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as CEO of XYZ, Inc., that the subject of this Traditional 510(k), the ABC Monitor, conforms with the following FDA-recognized standards:

- [Rec. Number 19-4] ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for safety and essential performance,
- [Rec. Number 19-1] ANSI/AAMI IEC 60601-1-2 Medical electrical equipment – Part 1-2 General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- [Rec. Number 12-293] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

All requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from each applicable standard were applied, and there were no differences between the tested device and the device to be marketed.

All tests were performed by [insert Testing Lab, and address if applicable].

Signed: *Jane Smith*
CEO, XYZ, Inc.

Date: October 25, 2018

Address: Medical Device Road,
Minneapolis, MN

Alternate Example of a Declaration of Conformity

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as CEO of XYZ, Inc., that the subject of this Traditional 510(k), the ABC Monitor, conforms with the following FDA-recognized standard:

> [Rec. Number 12-293] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

All *normative* requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from the standard were applied, and there were no differences between the tested device and the device to be marketed.

All tests were performed by [insert Testing Lab, and address if applicable].

Signed: *Jane Smith*
CEO, XYZ, Inc.

Date: October 25, 2018

Address: Medical Device Road,
Minneapolis, MN

Normative References

Why are normative references used in standards?

- Saves time
- Saves resources
- Promotes harmonization & uniformity

Normative References

What do we mean by a normative reference in a consensus standard?

- Bibliography (Informative)
- Normative References (Essential for understanding how to apply the standard.

Normative References

How do the requirements of a normative reference get incorporated?

- Referenced within the body of the text
- In its own section (Clause 2 if ISO)

Normative References

Do all the requirements apply and does the Declaration of Conformity have to include them all?

- Usually limited to a specific clause or clauses

Normative References

Does FDA recognition mean that all the normative requirements are automatically recognized?

- Only to the extent that they are used within the recognized standard
- Not automatically recognized independently

ISO/IEC 17050-2

ISO/IEC 17050-2 Conformity assessment – Part 2: Supplier's declaration of conformity – Supporting documentation

- Description of the object of the test
- Conformity assessment results including:
  - Description of the test method
  - If Good Laboratory Practices (GLPs) or Quality Systems Regulations (QSRs) were followed
  - Results
  - Assessment of the results including: choices, selections, adaptations, modifications or concessions made

Supplementary Information Sheet versus Supporting Documentation

Supplementary Information Sheet ≠ Supporting Documentation

- CDRH's determination of how the FDA-recognized standard may be used to satisfy a portion of the FD&C act
- Example: Describes a complete recognition or sections that are excluded from FDA's recognition

- Describes how the medical device conforms to the FDA-recognized standard
- Example: Describes acceptance criteria to demonstrate essential performance of a medical device

Supporting Documentation

Supporting documentation accompanies a Declaration of Conformity 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, for example, risk assessment

Supporting Documentation

Supporting documentation does NOT accompany a Declaration of Conformity when:

- The FDA-recognized standard includes both a test method and acceptance criteria
- Or, there is more than one standard, for example, one a test method and one with acceptance criteria
- The FDA-recognized standard is a design standard

FDA's Declaration of Conformity Review

- ISO/IEC 17050-1 elements or equivalent
- Standard is FDA-recognized
- No deviations made to normative requirements
- Standard is applicable to the device subject of the submission
- Supporting documentation, if necessary, per ISO 17050-2 or equivalent
- Data and information are in conformance with normative requirements
- Declaration of Conformity does not include a promissory statement

Why can FDA rely on a Declaration of Conformity?

- Section 301(x) of the FD&C Act
- Section 501(e)(2) of the FD&C Act
- Section 301(q)(2) of the FD&C Act
- 21 CFR Part 58 Good Laboratory Practices (GLPs)
- 21 CFR Part 820 Quality System Regulations (QSRs)
  - –Design validation, 21 CFR 820.30(g)
  - –Process validation, 21 CFR 820.75(b)
- Laboratory accreditation

Complete Test Reports Requested When

- A Declaration of Conformity is not provided
- Standard has neither a test method, nor predefined acceptance criteria
- Deviations to the normative requirements of the standard have been made

FDA Review of Declaration of Conformity and Supporting Documentation

Type of Consensus Standard for which a DOC might be provided		Should submission include test report?	Should submission include supplemental documentation per ISO/IEC 17050-2?
Design Standard		No	No
Standard Includes: *Test method or procedure*	*Acceptance Criteria*		
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

General Use of Consensus Standard

- No Declaration of Conformity elected
- Deviations
- Device was modified (adapted)
- Standard not recognized
- Submitter used an older version no longer recognized

When Standards Change

Before Review	During Review	After Review
Guidance encourages pre-submission (“Q-sub”)interactions	FDA will continue to review based on the previously recognized version	Changes to standards are not retroactive
Submitter’s should provide a strategy that addresses the differences between the older and the current version	If the new revision addresses new safety or effectiveness issue that is relevant to the final decision, FDA may ask the submitter to either meet the new requirement, or provide alternative data/information with a rationale.	Do not affect the status of clearance or approval
Focus is on issues that affect safety and/or effectiveness		Superseded standards that FDA has withdrawn may not be used with a Declaration of Conformity
		If the Submitter received clearance based on a Declaration of Conformity, but the standard is withdrawn, the device remains legally marketed.

Transition Periods

- Standards that have been withdrawn and replaced
- Specified amount of time
- Located in the Supplemental Information Sheet (SIS) below the extent of recognition
- Standards that impact Quality Systems Regulations or other horizontal processes will receive a 2-3 year transition
- Will consider ISO/IEC implementation/withdrawal dates

Why?

- Allows the submitter to continue to test and develop without additional retesting
- Allows time to revalidate processes under 21 CFR 820.75(b)
- Allows testing laboratories time to validate new test methods

Promissory Notes

- A statement in which the submitter indicates that the device is not yet known to be in conformance, but will conform before marketing
- Used in certain, limited situations. For example, installation requirements, expiration dating, chronic or long-term testing, post-market testing.
- Not appropriate for a Declaration of Conformity

Pending Recognitions

- FDA will periodically update the Recognized Standards Database for which recognition is pending
- FDA will follow-up pending recognitions with a Federal Register Notice
- Includes a Recognition Number
- Includes a Supplemental Information Sheet

Resources

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

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

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

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf

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

CDRH Learn: https://www.fda.gov/training/cdrhlearn/default.htm

FDA SMG 9100.1: www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm193332.htm

Questions?

Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading:

How to Study and Market Your Device, in the section called Standards