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

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Background

Voluntary consensus standards can be a valuable resource for industry and FDA staff. The use of consensus standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry for safe and effective medical products.

It is important to be aware that the use of consensus standards generally satisfies only a portion of a premarket submission. A submitter's use of consensus standards may not on its own provide a sufficient basis for regulatory decisions. FDA evaluates the totality of each submission to determine whether it contains all necessary information and meets the requirements for marketing or investigating the product in the United States.

Appropriate Uses of Consensus Standards in the Premarket Process:

- Declaration of Conformity (DOC) in accordance with section 514(c)(1)(B) of the FD&C Act
- General use

Declaration of Conformity

The purpose of declaring conformance with a consensus standard that FDA has recognized or decided to recognize is to use such conformance to meet certain premarket requirements and reduce the amount of supporting data and information that are submitted. FDA expects that all necessary testing required by the consensus standard will be performed and conformance to the consensus standard will be met prior to sending the premarket submission.

A DOC is an attestation that the device is in conformity. FDA recommends that most testing be conducted on a **final finished device**.

"Finished device" under 21 CFR 820.3(l) means 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. In contrast, **a final finished device** is a device that includes all manufacturing processes for the "to be marketed" device, including packaging and sterilization, if applicable.

If the tested device is not the final finished device the submitter intends to market, the submitter should provide a justification for any differences that may impact performance of the tested device compared to the final finished device to be marketed.

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

The elements that should be in a DOC are listed below. A submitter may choose to create a DOC using the format as described in ISO/IEC 17050-1 Conformity Assessment – Supplier's declaration of conformity – Part 1: General requirements. The elements that should be included are:

- Name and address of applicant/sponsor
- Product/device identification
- Statement of conformity (not compliance)

- List of standards applicable including options selected
- FDA recognition number for each standard
- Date and place of issuance of the Declaration of Conformity
- Signature, printed name
- Any limitation on the Declaration of Conformity

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 does NOT accompany a Declaration of Conformity when:

- The FDA-recognized standard includes both a test method and acceptance criteria
- 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

Although accompanying test data is not required to be submitted with a DOC, FDA may request, at any time, the data or information relied on by the submitter to make a DOC to a consensus 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
    - A statement in which the submitter indicates that the device is not yet known to be in conformance, but will conform before marketing

Complete Test Reports are 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

General Use of Consensus Standard

General use of a consensus standard in premarket submissions refers to situations where a submitter chooses to conform to a consensus standard, in part or in whole, but does not submit a DOC. Reasons for general use of a consensus standard vary, but may include:

- The manufacturer has chosen to use a recognized consensus standard without submitting a DOC;
- The manufacturer has made changes to the consensus standard methodology (i.e., deviations), relative to what FDA has recognized or decided to recognize, to adapt its purpose to test the device; or,
- The manufacturer has chosen to use a consensus standard that does not have a recognition number

Table 1 further outlines FDA's expectations regarding submission of supplemental documentation for different types of consensus standards that FDA has recognized or decided to recognize

Table 1 - FDA Review of Declarations of Conformity and Supplemental 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

Standards may be updated or revised, and the newer version recognized, during product development. This may present challenges to submitters. Table 2 below explains the impact when the standard change before, during and after the submission review.

Table 2 – Standard changes

<table>
<tr><th>Before Review</th><th>During Review</th><th>After Review</th></tr>
<tr><td>Guidance encourages pre-submission (“Q-sub”) interactions</td><td>FDA will continue to review based on the previously recognized</td><td>Changes to standards are not retroactive</td></tr>
<tr><td>Submitter’s should provide a strategy that addresses the differences between the older and the current version</td><td rowspan="3">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.</td><td>Do not affect the status of clearance or approval</td></tr>
<tr><td>Focus is on issues that affect safety and/or effectiveness</td><td>Superseded standards that FDA has withdrawn may not be used with a DOC</td></tr>
<tr><td></td><td>If the Submitter received clearance based on a Declaration of Conformity, but the standard is withdrawn, the device remains legally</td></tr>
</table>

If a submitter received clearance or approval based in part on a DOC, but the standard is withdrawn from recognition, the cleared or approved device remains legally marketed and it remains eligible (for 510(k)s) as a predicate device. However, any new device citing such a predicate in a 510(k) submission cannot similarly rely on a DOC to the withdrawn standard. In these circumstances, FDA will likely recommend that the submission use the newer version of the consensus standard, i.e., the version that has a current recognition number.

Example of a Declaration of Conformity

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as XX of XYZ, Inc., that the subject of this Traditional 510(k), the product XX, 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: XX
Title XX

Date: XX
Address: XX