On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

FDA notes that in particular, the QMSR does not utilize certain terms associated with specific record types, such as "Design History File (DHF)," "Device Master Record (DMR)," "Device History Record (DHR)," and "Quality System Record (QSR)." The elements that comprise those records are largely required to be documented by ISO 13485: 2016, including Clause 4.2 and its subclauses, and Clause 7 and its subclauses.

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.

The draft of this document was issued on May 13, 2014.

This document supersedes "Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards," issued on September 17, 2007, "Frequently Asked Questions on Recognition of Consensus Standards," issued on September 17, 2007, and "Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations," issued on March 12, 2000.

For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at 301-796-5900; or Scott Colburn at 301-796-6287 or by e-mail at scott.colburn@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2014-D-0456. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 17019 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) developed this document to provide guidance to industry and FDA staff about the appropriate use of national and international voluntary consensus standards (referred to as consensus standards) in the preparation and evaluation of premarket submissions for medical devices.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. 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. Consensus standards provide a consensus approach to certain aspects of the evaluation of device safety and effectiveness, such as testing methods, acceptance criteria, and processes to address areas such as risk management and usability. The use of consensus standards can also promote international harmonization. For decades, FDA has supported and relied on the development and

use of consensus standards to support the Agency's mission in protecting and promoting the public health.

A. The National Technology Transfer and Advancement Act (NTTAA)

In 1996, Congress passed the National Technology Transfer and Advancement Act (NTTAA) (Pub. L. No. 104-113), codifying an Office of Management and Budget (OMB) directive, Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, that had previously been issued several times, dating back to the late 1970s.[1] The NTTAA and OMB Circular A-119 established Federal government policies to improve the internal management of the Executive Branch by directing agencies to use voluntary consensus standards in lieu of government-unique standards except where voluntary consensus standards are inconsistent with law or otherwise impractical.[2]

B. The Food and Drug Administration Modernization Act and 21st Century Cures Act

Congress also enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. No. 105-115) and the 21st Century Cures Act (Pub. L. 114-255), which amended section 514(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 514(c) states, in part, that FDA "shall, 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," 21 U.S.C. 360d(c)(1)(A).

The term "recognize" in section 514(c) of the FD&C Act refers to FDA's formal identification of a standard after a determination that it is appropriate for manufacturers of products to declare conformance to meet relevant requirements in the FD&C Act, including premarket submission requirements.

This guidance refers to voluntary consensus standards recognized by FDA in the *Federal Register* in accordance with section 514(c) of the FD&C Act as "FDA-recognized consensus standards." A list of consensus standards that FDA has recognized or decided to recognize is available on the FDA Recognized Consensus Standards Database Web site.[3] See section IV for more information about standards that FDA has decided to recognize but for which recognition is still pending.

Use of consensus standards to meet premarket submission requirements can help facilitate the premarket review process and is not limited to use in Abbreviated Premarket Notifications (510(k)s), but can also be used for any 510(k), De Novo request, Investigational Device Exemption (IDE) application, Premarket Approval (PMA) application, Product Development Protocol (PDP), Humanitarian Device Exemption (HDE) application, Investigational New Drug

[1] See more information at https://www.nist.gov/standardsgov/what-we-do/federal-policy-standards/key-federal-directives.
[2] Pub. L. No. 104-113, 110 Stat. 775, 783, § 12(d) (March 7, 1996).
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

(IND) Application, or Biologics License Application (BLA) for those devices that are regulated by CBER as biological products under section 351 of the Public Health Service (PHS) Act. However, in most cases the standards would only satisfy part of the submission requirements. In addition, submitters may choose to conform to applicable consensus standards or address issues relevant to approval or clearance in another manner.[4] Regardless of the decision a submitter ultimately makes about the use of consensus standards, submitters should make sure their premarket submissions contain all necessary information, as required by the FD&C Act and its implementing regulations.[5]

III. Scope

This guidance describes the appropriate use and documentation of both FDA-recognized and non-recognized consensus standards for premarket submissions and how FDA staff intends to rely on consensus standards during the review process. This guidance provides further clarity and explanation about the regulatory framework, policies, and practices regarding the appropriate utilization of consensus standards for premarket submissions. This guidance is applicable to all articles that meet the definition of a device under section 201(h) of the FD&C Act.

Under section 514(c) of the FD&C Act, conformity with consensus standards can fulfill requirements other than premarket submission requirements; this use is not discussed in this guidance. This guidance also does not address the specific content required in a particular premarket submission. Additionally, this guidance does not address consensus standards that are incorporated by reference (IBR) into regulations (e.g., 21 CFR 830.10, *Incorporation by reference* regarding requirements for a Unique Device Identifier). For additional information, see the Standards Incorporated by Reference Database Website.[6]

IV. Use of Consensus Standards

This section discusses procedures for the appropriate use of consensus standards, the content of a Declaration of Conformity (DOC) to consensus standards that FDA has recognized or decided to recognize, and the general use of standards when the use of a DOC is not appropriate for purposes of premarket submissions.

The use of consensus standards is not mandatory for medical device premarket submissions unless the consensus standard has been incorporated by reference into a regulation. A manufacturer may choose to rely on applicable consensus standards or address issues relevant to approval or clearance in another manner. As discussed below, if a manufacturer chooses to submit a DOC under section 514(c)(1)(B) of the FD&C Act, the declaration must be truthful.[7]

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[4] In the context of this guidance, "submitter" may refer to the holder of a premarket submission, manufacturer, sponsor, or applicant.

[5] In the case of a device regulated as a biologic under a BLA by CBER, additional information may be required under the PHS Act.

[6] https://standards.gov/sibr/query/index.cfm

[7] Under section 301(x) of the FD&C Act, the falsification of a Declaration of Conformity submitted under section 514(c) of the FD&C Act is a prohibited act. Under section 501(e)(2) of the FD&C Act, a device is adulterated if, among other conditions, it is declared to be in conformity with a recognized consensus standard unless the device is in all respects in conformity with such standard.

It is important for industry and FDA staff 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. For example, a specific device may raise safety and/or effectiveness questions not addressed by any FDA-recognized consensus standard or a specific FDA regulation may require additional information beyond what the FDA-recognized consensus standard provides. In other words, even when a premarket submission appropriately demonstrates conformity with one or more consensus standards, such conformity may not satisfy all requirements under the FD&C Act and its implementing regulations for marketing or investigating the product in the United States. 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.

FDA's experience with premarket submissions indicates that submitters do not always use consensus standards appropriately. For example, submitters may use a version of a consensus standard that FDA does not recognize, or they may not realize that only certain aspects—not all—of a particular consensus standard have been recognized by FDA.[8] In addition, submitters sometimes attempt to use consensus standards that do not apply to the particular type of device or testing performed. When submitters do not use consensus standards appropriately, it is often necessary for FDA staff to request additional information to address the issue(s) the standard was intended to address.

Appropriate use of consensus standards can be effective in demonstrating individual aspects of safety, effectiveness, or substantial equivalence in the premarket process. When used appropriately, consensus standards will typically reduce the amount of documentation that a submitter needs to provide and may reduce FDA review time.

There are two appropriate uses of consensus standards in the premarket process: Declaration of Conformity in accordance with section 514(c)(1)(B) of the FD&C Act and general use.

A DOC may refer only to standards for which FDA has assigned a recognition number. Such standards are those that FDA has recognized by notice published in the *Federal Register* or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the *Federal Register*). A submitter may consult FDA's online database for Recognized Consensus Standards to determine whether a DOC may refer to a particular standard. The database will provide the most up-to-date list of suitable standards because, after FDA has decided to recognize a standard, we will update our online database to reflect the decision even before recognition of the standard. The database will include a recognition number and a Supplemental Information Sheet (SIS) for each decision, including for cases for which recognition is pending.

[8] FDA recognizes specific versions of a consensus standard, and the recognized version may not always be the most current or be for all clauses of a standard. Please refer to the consensus standard database Web site, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm that contains supplementary information.

A DOC to a consensus standard may be used when a submitter certifies that its device conforms to all of the requirements of a consensus standard that FDA has recognized or decided to recognize.[9] In a DOC, the submitter may not deviate from the consensus standard that FDA has recognized or decided to recognize.[10]

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. Also, a submitter may not submit a DOC if the submitter chose to rely on a consensus standard that FDA has not recognized or decided to recognize, or the submitter has deviated from an FDA-recognized consensus standard.

A. Use of Declarations 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 to FDA. Thus, under section 514(c)(1)(B) of the FD&C Act, a submitter who chooses to rely on a consensus standard in a DOC to meet a premarket submission requirement must at the time of the submission certify that the device is in conformity with the consensus standard that FDA has recognized or decided to recognize so that FDA may determine in its review whether the submission meets applicable premarket requirements. 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. To certify conformance with a consensus standard, the submitter must submit a DOC (see section 514(c)(1)(B) of the FD&C Act). These elements of a DOC[11] are consistent with ISO/IEC 17050-1 *Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements* and ISO 17050-2 *Conformity assessment – Part 2: Supporting documentation for the general requirements and supporting documentation* needed for the submission of a DOC to a consensus standard.

When submitters are interested in making a DOC to a consensus standard, and the device type is not included within the scope of that standard and is not listed in the SIS, the submitter should explain why that consensus standard is appropriate for the device in question. In most circumstances, the scope of the standard defines what is to be tested, whether that is the device itself, or an attribute of that device, e.g., the device's material composition/properties or packaging. 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. The DOC may be based on data or information provided by

[9] See section 514(c)(1)(B) of the FD&C Act.
[10] See sections 301(x) and 501(e)(2) of the FD&C Act.
[11] ISO/IEC Guide 22:1996 *General criteria for supplier's declaration of conformity* was revised and replaced by ISO/IEC 17050-1:2004. See https://www.iso.org/iso/catalogue_detail.htm?csnumber=27569.

the component manufacturer(s), but it is the responsibility of the submitter to ensure the accuracy of the information. In these instances, FDA recommends that submitters consult with the appropriate FDA staff prior to initiating testing. Information for requesting feedback may be found in the guidance titled *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff*.[12]

A submitter may base a DOC on testing and analysis performed in-house or on testing performed by a third party, such as a testing laboratory or certification body. If a submitter used a third party, the submitter should provide the name and address of each testing laboratory or certification body that was involved in determining the conformance of the device with the applicable consensus standard(s) that FDA has recognized or decided to recognize and reference any accreditations of those organizations.

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 (see section 514(c)(3)(B) of the FD&C Act). However, these requests should only occur in certain cases, as described below in sections IV.A(2) and (3) of this guidance. The submitter must maintain all records that include data and information demonstrating conformity, whether based upon third-party or in-house testing, to the consensus standard that FDA has recognized or decided to recognize in accordance with the Quality System Regulation (21 CFR part 820). Such records are part of the design history file for the device and are subject to inspection in accordance with 21 CFR 820.180.

Falsifying a DOC to a consensus standard is a prohibited act under section 301(x) of the FD&C Act. If a DOC to a consensus standard has been falsified, or if the device does not conform to the standard as declared, purported, or represented, the device would be deemed adulterated under section 501(e)(2) of the FD&C Act. Also, intentionally or unintentionally falsifying a DOC to obtain device clearance or approval is a prohibited act under section 301(q)(2) of the FD&C Act.

(1) Elements of a Declaration of Conformity

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:

a. Name and address of the applicant/sponsor responsible for the DOC
b. Product/device identification, including product codes, device marketing name, model number and any other unique product identification data specific to the DOC in question
c. Statement of conformity
d. A list of standards for which the DOC applies including, for each standard, the options selected, if any
e. The FDA recognition number for each standard
f. The date and place of issuance of the DOC

[12] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

g. Signature, printed name, and function of the sponsor responsible for the DOC
h. Any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes)

(2) Supplemental Documentation to Support a Declaration of Conformity

Not all consensus standards that FDA has recognized or decided to recognize are appropriate for DOCs without the submission of supporting documentation that describes how the device conforms to the consensus standard. It is important to restate that the use of consensus standards may satisfy only a portion of a premarket submission and conformance to a standard on its own may not provide a sufficient basis for a regulatory decision. Many consensus standards that FDA has recognized or decided to recognize, while useful in the premarket process, are too general and broad in scope for FDA to determine whether conformance to the applicable consensus standard has been met or whether conformance to the consensus standard alone is sufficient to make a regulatory decision, unless FDA also reviews the underlying data or supporting documentation. Types of consensus standards where review of the underlying data may be necessary may include standards that are horizontal, are process-oriented, or that include choices relating to test methods, test selection, or have guidelines that apply to a broad range of device types and safety issues. An example is ISO 14971 *Medical devices – Application of risk management to medical devices*. These consensus standards typically do not list all of the detailed acceptance criteria for the necessary performance tests. In cases where the consensus standard is not well-suited for a DOC without the submission of supporting documentation, the FDA recommends that submitters follow ISO/IEC 17050-2 *Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation*. In brief, if a premarket submission contains a DOC to such a consensus standard, FDA recommends including a summary test report that includes test results. Similarly, for consensus standards that describe test methods, a process, or consists of guidelines, but do not provide specific acceptance criteria for all of the necessary performance tests, the supporting documentation should be submitted, for example, ANSI/AAMI/IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

Many standards, called "parent" standards, have accompanying consensus standards (e.g., IEC collateral[13] and particular[14] standards, or standards within a series such as ANSI/AAMI/ISO 80369 *Small-bore connectors for liquids and gases in healthcare applications* series) that provide acceptance criteria for the testing of specific types of devices (e.g., ANSI/AAMI/ISO 80369-3 *Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for*

[13] An IEC collateral standard is defined as a standard that addresses additional basic safety and essential performance requirements that are common to a subgroup of medical electrical equipment; or a standard that addresses additional basic safety and essential performance requirements that deal with characteristics of medical electrical equipment or medical electrical systems that are not fully covered by the general standard. See ANSI/AAMI ES60601-1:2005/(R) 2012 and A1 2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text): *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, MOD).

[14] An IEC particular standard is defined as a standard that addresses additional basic safety and essential performance requirements that deal with characteristics of particular medical electrical equipment that are not covered by the general standard.

enteral applications). These accompanying consensus standards, if recognized by FDA, may be appropriately suited for DOCs without submission of underlying data.

(3) FDA Review of Declarations of Conformity and Supplemental Documentation

During review of a premarket submission in which a DOC has been submitted, FDA will review the DOC and determine whether the following have been met:

a. The elements in this guidance, ISO/IEC 17050-1, or equivalent, of a Declaration of Conformity are present.
b. The standard(s) identified in the DOC has (have) a recognition number.[15]
c. There have been no deviations made to the normative part of the consensus standard(s) identified.
d. The consensus standard(s) identified in the DOC is (are) applicable to the medical device under review.[16]
e. The supportive documentation, if determined to be necessary per ISO/IEC 17050-1, is provided according to ISO/IEC 17050-2 or equivalent (see Table 1 below).
f. The data or information submitted to support such declaration demonstrates that the device is in conformity with the normative section of the standard.[17]
g. The DOC does not include a promissory statement (See Section VI).[18]

If any of the elements above are not met, FDA will review any explanation provided by the sponsor to determine if it is adequate to support the DOC or will request additional information to meet the requirements.

As outlined above, there are circumstances when supplemental documentation is necessary to support a DOC. The type of information a sponsor should submit and the FDA needs to review as supplemental documentation will vary based on the specific consensus standard; however, the following general principles should govern the need for and review of supplemental documentation:

- When the consensus standard includes both a test method or test procedure with a single set of predefined acceptance criteria, FDA should generally not request the data relating to the specific consensus standard identified in the DOC.
- When the consensus standard describes a test method or procedure, but does not include acceptance criteria, the submitter should provide an assessment of the results and how conformity was determined.
- When the consensus standard includes choices related to, for example, what is to be tested, which test methods to use, or acceptance criteria to assess conformity, the submitter should include an explanation for the choices and selections made.

[15] See section 514(c)(1)(B) of the FD&C Act.
[16] See section 514(c)(3)(A)(ii) of the FD&C Act.
[17] See section 514(c)(3)(A)(i) of the FD&C Act.
[18] See section 514(c)(1)(B) of the FD&C Act.

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[19]

Type of Consensus Standard for which a DOC might be provided in a premarket submission		Should submission include complete test report?	Should submission include supplemental documentation per ISO/IEC 17050-2?
Design Standard		No	No
Standard Includes—			
Test Method(s) or Procedure(s)	*Acceptance Criteria*		
Included	Not included	No	Yes, criteria/ summary results
Not included	Included	No	Yes
Included	Included	No	No
Not included	Not Included	Yes	Yes, complete test report

B. General Use of Consensus Standards

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: (1) the manufacturer has chosen to use a recognized consensus standard without submitting a DOC; (2) 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, (3) the manufacturer has chosen to use a consensus standard that does not have a recognition number (e.g., because there is no consensus standard applicable to the device type that FDA has recognized or decided to recognize). When a manufacturer is citing the general use of a voluntary consensus standard as discussed above, we recommend that the basis of such use be included along with the underlying information or data that supports how the standard was used.

[19] Although Table 1 represents FDA's general approach, consistent with section 514(c)(3)(B) of the FD&C Act, FDA may request, at any time, the data or information relied on by a person to make a declaration of conformity with respect to a recognized standard.

V. Managing Product Development When Standards Change: Transition Periods

As FDA and industry recognize the need to improve device performance or address noted safety issues, consensus standards may become obsolete or need updating to reflect current knowledge. FDA recognizes that changes to existing standards may affect the lifecycle of device development, and the Agency's recognition of an updated version of an existing consensus standard or the recognition of a different consensus standard altogether, without an approach to manage this transition, may delay product development.

When a consensus standard has been replaced by a newly recognized standard, the older version will be withdrawn following a transition period. The transition period is intended to decrease the burden of implementing a shift from one version of a consensus standard to a newer version. Such a transition period allows the submitter to continue using an earlier version of a consensus standard while preparing to use a newer version of the same consensus standard that may have significant changes. By providing transition periods, FDA enables the submitter to continue current product development and testing potentially without having to conduct additional testing due to a newer version of a consensus standard having been published and recognized. Due to the differences between standards, a justification for use of the older version of the standard should be provided when a newer version of the standard raises significant questions that were not previously addressed.

A. Where to Find Information on a Transition Period

The transition period will be found within the SIS and will provide the name of the outgoing version of the consensus standard, the name of the newer version of the consensus standard, and the date the transition period expires. The length of the transition period will be listed in the SIS at the time of recognition of the newer consensus standard. An example of a transition period statement that will be included in the SIS for both standards is:

> "FDA recognition of [the outgoing version of the consensus standard] will be superseded by recognition of [the newer version of the FDA-recognized consensus standard]. FDA will accept Declarations of Conformity, in support of premarket submissions, to [the outgoing version of the consensus standard] until [Month, Date, and Year]. After this transition period, Declarations of Conformity to [the outgoing version of the consensus standard] will not be accepted."

B. When Standards Change Prior to Review of a Premarket Submission

FDA understands that standards may be updated or revised, and the newer version recognized, during product development. This may present challenges to submitters. FDA values and encourages early interaction with submitters to ensure scientific issues are addressed prior to the submission of a marketing application for a device, including a discussion of the changing standard. The submitter is encouraged to engage the Agency regarding the strategy for addressing

the differences between the two versions of the standard and whether those differences significantly affect the evaluation of safety and effectiveness. This is because it may not be necessary to comply with all parts of the revised standard, only those parts that significantly affect the evaluation of safety and effectiveness.

C. When Standards Change During Active Review of a Premarket Submission

Generally, while a submission is undergoing active review, and in the interim before a consensus standard is updated or revised and recognized, FDA will continue to review that submission based on the previously FDA-recognized version. If the updated or revised consensus standard addresses a new safety or effectiveness issue that is relevant to the final decision of that submission, FDA may ask the submitter to either meet the portions of the new or updated standard that address that safety or effectiveness issue, or provide alternative data or information along with a scientific rationale for why the alternative addresses the issue.

D. Transition Period Expiration

FDA will withdraw recognition of an outdated consensus standard in accordance with section 514(c)(2) of the FD&C Act at the end of a transition period. Submitters should check the FDA Recognized Consensus Standards Database Web site often to ensure that their forthcoming premarket submissions utilize the appropriate version of a consensus standard. If a submission is submitted to FDA after the transition period has expired, as noted in the SIS, FDA expects that testing will be completed using a standard with a current recognition number. Statements declaring conformance to expired or earlier versions of the consensus standard will generally not be accepted. It is expected that by the transition period expiration date, submitters will be able to meet the performance specifications of the newer version of the consensus standard.

VI. Promissory Statements

For purposes of this guidance, a "promissory statement" is defined as a statement in which the submitter indicates that the device is not yet known to be in conformance with a consensus standard at the time of the premarket submission but will conform to the consensus standard prior to marketing. FDA believes that in many cases the use of a promissory statement indicating future conformance with a consensus standard is not appropriate to support a premarket submission. This is because many standards include general methods with multiple options, and in some cases, these standards do not include well-defined acceptance criteria or address assessment of results. Typically, if submitters rely on a consensus standard to support a premarket submission, FDA expects that conformance to the consensus standard will be met prior to submission of the application to FDA. However, in some limited cases, a promissory statement may be acceptable to support a regulatory decision. If it is determined that use of a promissory statement is appropriate, it should include a statement that the device will not be marketed until conformance has been confirmed.

Although a promissory statement describes a situation where a submitter states that they will conform to a consensus standard that FDA has recognized or decided to recognize, submitters

may not use a DOC along with a promissory statement. Under section 514(c) of the FD&C Act, submitters may only use a DOC to a consensus standard if conformance has been met prior to the submission of the application to FDA. It is important to note that, in cases where FDA accepts promissory statements, manufacturers must still comply with the obligations under the quality system regulation in 21 CFR part 820, including design validation, 21 CFR 820.30(g), and process validation, 21 CFR 820.75(b), by which a manufacturer must also establish and maintain procedures for validating a device design and monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

VII. Limitations of Consensus Standards

A specific device may raise issues not addressed by consensus standards. For example, submissions for some devices may rely on data from animal testing or clinical studies not addressed in consensus standards that FDA has recognized or decided to recognize. In other instances, additional performance specifications may be applicable to the device that is the subject of the submission. Additional information to support approval or clearance of a device may also be recommended in guidance documents. When a submission contains a submitter's DOC with one or more consensus standards, FDA reviews the premarket submission to ensure that the DOC is appropriate and that the premarket submission contains all of the other necessary information for FDA to evaluate the safety and effectiveness or, in the case of a 510(k), the substantial equivalence of the device.

It is important to note that consensus standards with requirements and/or references to other normative requirements do not have precedence over existing FDA laws and regulations.

VIII. When Devices or Standards Change After Marketing Authorization

Just as standards may be revised before submission of an application to FDA, they may also be revised after marketing authorization is granted. Changes in a recognized consensus standard do not retroactively affect a product's clearance or approval status. Furthermore, once a consensus standard is recognized, recognition of its revisions will not be automatic. In general, FDA actively assesses the impact of new consensus standards and revisions of existing standards on the premarket review process and recognizes these standards, as appropriate. As FDA determines that new or revised standards are appropriate for meeting requirements under the FD&C Act for medical devices, we will update the standards database on FDA's website. As explained above, once we have decided to recognize a standard, we will issue a recognition number and provide supplemental information in the database. To recognize such standards, we will periodically publish a recognition list in the *Federal Register*. FDA usually performs this activity at least twice annually. Superseded standards that FDA has withdrawn from the list of recognized standards cannot subsequently be used in DOCs.

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.