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

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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 Scott Colburn at 301-796-6287 or by e-mail at scott.colburn@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

Preface

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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 1770 to identify the guidance you are requesting.

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

The Food and Drug Administration (FDA) developed this draft document to provide guidance to industry and FDA reviewers about the appropriate use of national and international voluntary consensus standards[1] (referred to as consensus standards) in the preparation and evaluation of premarket submissions for medical devices.

When finalized, this guidance will supersede the *Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards* which was issued on September 17, 2007. Additional guidance on the recognition process can be found in the following guidance documents: *Frequently Asked Questions on Recognition of Consensus Standards* (September 17, 2007) and *CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition* (September 17, 2007).

Web site addresses for all hyperlinked material in this draft guidance document can be found in the List of References at the end of this document.

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

[1] OMB Circular No. A-119, Revised: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, February 10, 1998.

viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. 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, pass/fail performance 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.

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 (OMB 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. 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]

Congress also enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. No. 105-115). FDAMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 514(c), 21 U.S.C. 360d(c), which states:

> (1)(A) In addition to establishing a performance standard under this section, the [FDA[3]] 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 under this chapter to which such standard is applicable.
>
> (B) If a person elects to use a standard recognized by the [FDA] under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the [FDA] that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter.

[2] Pub. L. No. 104-113, 110 Stat. 775, 783, at § 12(d) (March 7, 1996).

[3] In light of section 1003(d) of the FD&C Act, 21 U.S.C. 393(d), and the Secretary of Health and Human Services' (the Secretary's) delegation to the Commissioner of Food and Drugs, references to the "Secretary" in section 514(c) of the FD&C Act have been changed to the "FDA."

(2) The [FDA] may withdraw such recognition of a standard through publication of a notice in the Federal Register if the [FDA] determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter.

(3)(A) Subject to subparagraph (B), the [FDA] shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the [FDA] finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The [FDA] may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the [FDA] or a period equal to the expected design life of the device, whichever is longer.

The term "recognize" in section 514(c) of the FD&C Act refers to FDA's identification of standards as appropriate for manufacturers of medical devices to declare conformance to meet relevant requirements in the FD&C Act, including premarket submission requirements.

This guidance refers to 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 current FDA-recognized consensus standards is available on the FDA Recognized Consensus Standards Database Web site.

Use of consensus standards to meet premarket submission requirements can help facilitate the premarket review process, i.e., Premarket Notification (510(k)), *De Novo* classification request, Investigational Device Exemption application (IDE), Premarket Approval application (PMA), Product Development Protocol (PDP), Humanitarian Device Exemption application (HDE), or Investigational New Drug (IND) Application and 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, but in most cases the standards only satisfy part of the 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.

3. Scope

[4] In the context of this draft guidance, "submitter" may refer to the 510(k) holder, manufacturer, or sponsor.

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 medical device premarket submissions.

Under section 514(c) of the FD&C Act, compliance with FDA-recognized consensus standards can fulfill requirements other than premarket submission requirements, which 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 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.

4. Use of Consensus Standards

This section discusses procedures for the appropriate use of consensus standards, both recognized and non-recognized, limitations on the use of consensus standards, and the content of a Declaration of Conformity to FDA-recognized consensus standards for purposes of premarket submissions.

In general, the use of consensus standards is not mandatory for medical device premarket submissions.[5] 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 Declaration of Conformity to an FDA-recognized consensus standard under section 514(c)(1)(B) of the FD&C Act, the declaration must be truthful.[6]

It is important for industry and FDA reviewers to be aware that the use of consensus standards is generally only one part of a premarket submission. A submitter's use of consensus standards may not on its own provide sufficient basis for regulatory decisions; e.g., 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 may not realize that only certain aspects — not all — of a

[5] There are exceptions, for example, when a consensus standard has been incorporated by reference into regulation.
[6] Under section 301(x) of the FD&C Act, 21 U.S.C. 331(x), the falsification of a Declaration of Conformity submitted under section 514(c) of the FD&C Act is a prohibited act.

particular consensus standard have been recognized by FDA.[7] 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 review 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. Under such use, 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 Declaration of Conformity to an FDA-recognized consensus standard can be used when a submitter certifies that its device conforms to all of the requirements of an FDA-recognized consensus standard except for inapplicable requirements. In a Declaration of Conformity, the submitter may not deviate from the FDA-recognized 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 Declaration of Conformity. A submitter may not submit a Declaration of Conformity if the submitter chose to rely on a consensus standard that has not been recognized by FDA under section 514(c)(1)(A) of the FD&C Act or the submitter has deviated from an FDA-recognized consensus standard. Reasons for general use of a consensus standard vary, but may include: (1) the manufacturer has chosen to use a non-recognized consensus standard (e.g., because there is no FDA-recognized consensus standard applicable to the device type); or (2) the manufacturer has made changes to the FDA-recognized consensus standard methodology to adopt its purpose to test the device.

4.1 Use of FDA Form 3654: "Standards Data Report for 510(k)s" (Standards Data Report Form)

Premarket notification submitters referencing any consensus standard should include a completed Standards Data Report for 510(k)s (FDA Form 3654) as part of their submission. The Standards Data Report Form is intended to help FDA staff understand how the submitter has applied a consensus standard to the medical device under review and assess whether the information submitted supports a substantial equivalence determination.

To reduce additional information requests in the review of the submission, submitters should provide the following clarifying information when filling out the form:

- Properly identify the consensus standard by its complete title, including, as appropriate, any relevant amendments and corrigendum, and whether it is FDA-recognized.

[7] FDA recognizes specific versions of a consensus standard, and the recognized version may not always be the most current.

    - For FDA-recognized consensus standards, explain how the Supplemental Information Sheet (SIS), including the Extent of Recognition, was incorporated into the use of the standard.
    - For non-recognized standards, explain how that standard applies to the medical device for its intended use.
- Where a consensus standard contains options (e.g., multiple test methods or pathways to demonstrate conformity to a standard), provide the rationale for the selected option.
- Provide adequate justification for any deviations in the summary test report.
- Provide adequate justification for any differences that may exist between the tested device and the device to be marketed.
- For consensus standards that do not state acceptance criteria or established end points, include appropriate justification for the acceptance criteria used and provide a summary test report.

4.2 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 if a submitter is far into the development path of a new device, 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, can delay product development.

Recognition of certain updated consensus standards may require a transition period for a submitter to be able to fully implement 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 with significant changes. In most cases for vertical consensus standards, updated versions of consensus standards may be implemented with minimal disruption because both industry and FDA would have worked together in the standards development process to update the consensus standard; as such, these standards typically do not need a transition period. However, where the consensus standard is horizontal, complex and/or comprehensive, a transition period may be established by FDA in consultation with industry to ensure a smooth transition to the newer consensus standard. A transition period allows the submitter to continue current product development and testing without having to conduct additional testing due to a newer version of a consensus standard having been published and recognized.

If a transition period has been established, it will be listed in the SIS at the time of recognition of the newer consensus standard. The transition period represents the best estimate by FDA of a reasonable period of time for most device manufacturers to make the transition to the newer standard based on the types of devices affected by the change and their expected development cycles. The transition period will be found within the "Extent of Recognition" section 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. An example of a transition period statement is:

> "FDA recognition of [the complete name of the outgoing version of the consensus standard] is hereby superseded by recognition of [the complete name of the newer version of the consensus standard]. FDA will accept declarations of conformity in support of premarket submissions, to [the complete name of the outgoing version of the consensus standard] until [Month Date, Year]. After this transitional period, declarations of conformity to [the complete name of the outgoing version of the consensus standard] will not be accepted."

FDA will withdraw recognition of the outdated consensus standard in accordance with section 514(c)(2) of the FD&C Act at the end of the transition period.

Submitters should check the FDA Recognized Consensus Standards Database often to ensure that their new 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 the current FDA-recognized consensus standard. Declarations of Conformity to the earlier and obsolete version of the consensus standard will generally not be accepted. FDA may request additional data or information to support the premarket submission if the submitter does not cite the current recognized version of the consensus standard and the data and information provided in the submission do not fully address the relevant issue. It is expected that by the transition period expiration date, submitters will be able to meet the requirements of the newer FDA-recognized version of the consensus standard.

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. If the Agency has had prior interaction with a submitter where a then recognized consensus standard was going to be used to support clearance/approval and a newer version of the consensus standard or a different consensus standard is recognized before submission or during the review process, FDA may permit a submitter to use the previously recognized consensus standard beyond the transition period.

Generally, if a submission is under active review when a new consensus standard or updated version of an existing consensus standard is recognized, FDA will continue to review that submission based on the previously recognized consensus standard. However, if a known safety issue is addressed by a new or updated consensus standard, for a submission under review FDA may ask the submitter to meet the portions of the new or updated consensus standard that specifically address that safety issue or to otherwise provide information or data to address that issue.

4.3 Supplemental Information Sheet

FDA developed the Supplemental Information Sheet (SIS) as a tool for identifying how the FDA-recognized consensus standard(s) applies to a medical device under review. Each FDA-recognized consensus standard is accompanied by a unique SIS, which provides information on the following general topics:

- FDA's extent of recognition of the consensus standard;

- The types of devices or device categories addressed by the standard;
- Transition period, if applicable; and
- Relevant guidance.

When considering the use of an FDA-recognized consensus standard, the submitter should examine the SIS which can be accessed through the FDA Recognized Consensus Standards Database. The use of the SIS should assist the submitter in the appropriate use of and conformance to an FDA-recognized consensus standard.

4.4 Use of Declarations of Conformity for FDA-Recognized Consensus Standards

The purpose of declaring conformance with an FDA-recognized consensus standard 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 an FDA-recognized consensus standard to meet a premarket submission requirement must at the time of the submission certify that the device is in conformity with the FDA-recognized consensus standard so that FDA can 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 the premarket submission. To certify conformance with an FDA-recognized consensus standard, the submitter must submit a Declaration of Conformity (see section 514(c)(1)(B) of the FD&C Act).

Through the use of a Declaration of Conformity, industry may be able to avoid submission of underlying data demonstrating conformance to that standard. The use of consensus standards can help streamline and increase consistency in the premarket review regarding certain aspects of the evaluation of device safety and effectiveness. However, a submitter's improper use of consensus standards may result in failure to provide meaningful or sufficient information about a device under review and as such hinder, rather than facilitate FDA's review of the submission. FDA is providing additional clarification to enhance the effective use of consensus standards in premarket submissions.

If a submitter intends to submit a Declaration of Conformity to an FDA-recognized consensus standard, the submitter should use the consensus standard to assess certain aspect(s) of the safety, effectiveness, or substantial equivalence of a medical device to meet a premarket submission requirement (see section 514(c)(1)(B) of the FD&C Act). A submitter may submit a Declaration of Conformity for a device that is not listed in a SIS for an FDA-recognized consensus standard. The Review Division will determine whether the Declaration of Conformity to the FDA-recognized consensus standard is appropriate for that device. To allow proper evaluation, the submitter should justify why that consensus standard is appropriate for the device in question.

With the Declaration of Conformity, the submitter is certifying that the device conforms to all of the requirements of the FDA-recognized consensus standard except for identified inapplicable requirements. Therefore, the Declaration of Conformity should state that all requirements were met and identify all inapplicable requirements. An appropriate justification should be provided for each

inapplicable requirement (e.g., the test method is specific to stainless steel and the submitter's device is made from nitinol). A Declaration of Conformity should be submitted for each FDA-recognized consensus standard used in a submission.

There are times when deviations from an FDA-recognized consensus standard are necessary to support the performance and/or claims of the device. Where a submitter deviates from an FDA-recognized consensus standard, a Declaration of Conformity should not be used. Submitters that deviate from FDA-recognized consensus standards should identify the consensus standard used, identify the deviation(s) (for 510(k)s, submitters should identify the consensus standards and deviations using FDA Form 3654), and provide the appropriate underlying data in the submission to support the appropriate use of the standard.

To support a Declaration of Conformity to an FDA-recognized consensus standard, FDA recommends that testing be conducted on a finished device.[8] If the tested device is not the same as the finished device the submitter intends to market, the submitter should provide a scientific rationale for the applicability of the test results to the finished device. In such instances, FDA recommends that submitters consult with the appropriate FDA Review Division prior to initiating testing.

A submitter may base a Declaration of Conformity on its own testing and analysis or on that of 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 FDA-recognized consensus standards and reference any accreditations of those organizations.

While accompanying test data may not be required with a Declaration of Conformity, FDA may request, at any time, the data or information relied on by the submitter to make a Declaration of Conformity to an FDA-recognized consensus standard (see section 514(c)(3)(B) of the FD&C Act). However, this should only occur in certain cases, as described below in sections 4.5 and 4.6. The submitter must maintain all records that include data and information demonstrating conformity, whether based upon third party or in-house testing, to the FDA-recognized consensus standard for two years after clearance or approval of the device or for the expected design life of the device, whichever is longer (section 514(c)(3)(C) of the FD&C Act). The records are part of the design history file for the device and are subject to inspection under 21 CFR 820.180.

Falsifying a Declaration of Conformity to an FDA-recognized consensus standard is a prohibited act under section 301(x) of the FD&C Act, 21 U.S.C. 331(x). Any device for which a Declaration of Conformity to an FDA-recognized consensus standard has been falsified or that is not in all respects in conformity with such standard is adulterated under section 501(e)(2) of the FD&C Act, 21 U.S.C. 351(e)(2). Also, the intentional or unintentional submission of a false report, including a Declaration of Conformity that is used to obtain device clearance or approval, is a prohibited act under section 301(q)(2) of the FD&C Act, 21 U.S.C. 331(q)(2).

[8] "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.

4.5 FDA Review of Declarations of Conformity

When an FDA-recognized consensus standard describes a test method, but does not include specific performance limits or pass/fail criteria, the submitter should provide the test results in its premarket submission to FDA. If the FDA-recognized consensus standard includes performance limits or acceptance criteria, FDA would most likely not request the data relating to the specific consensus standard cited in the premarket submission.

However, there may be circumstances when FDA has specific concerns about the adequacy of the Declaration of Conformity to address the conformance of the device under review. If a submitter declares conformance to an FDA-recognized consensus standard, but information in the submission raises questions about the extent of conformity, then FDA may request the underlying[9] data to assess the performance of the device relative to the consensus standard.

4.6 Consensus Standards Not Well-Suited for Declarations of Conformity without Submission of Underlying Data

Not all FDA-recognized consensus standards are appropriate for Declarations of Conformity without the submission of underlying data. Some FDA-recognized consensus standards, 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 unless FDA reviews the underlying data (for example, standards that are horizontal or process oriented or have guidelines that apply to a broad range of devices and safety issues). As a result, these consensus standards typically do not list all of the detailed acceptance limits/criteria for the necessary performance tests. If a premarket submission contains a Declaration of Conformity to such a consensus standard, FDA is likely to request additional information, including test results. Similarly, FDA-recognized consensus standards that describe test processes or guidelines, but do not provide specific pass/fail criteria for all of the necessary performance tests are generally not appropriate for Declarations of Conformity without submission of underlying data.

Many consensus standards have accompanying consensus standards (e.g., IEC collateral[10] and particular[11] standards, or standards within a series such as the ISO 10993 series) that provide acceptance criteria for the testing of specific types of devices. These accompanying consensus standards, if recognized by FDA, may be appropriately suited for Declarations of Conformity without submission of underlying data.

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[9] For purposes of this document, underlying data means the data and/or information that were used to support the Declaration of Conformity.

[10] 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—Part1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, MOD).

[11] 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. (See footnote 10 for citation.)

5. 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 in conformance with a consensus standard at the time of the premarket submission but will conform to the consensus standard prior to marketing. Often, this promissory statement is accompanied with a statement that the device will not be marketed until conformance has been determined at some future date after clearance or approval of the device by FDA. FDA believes that the use of a promissory statement indicating future conformance with a consensus standard is not appropriate to support a premarket submission. 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 the submission.

6. Limitations of Consensus Standards

A specific device may raise issues not addressed by consensus standards. For example, submissions for some devices may require data from animal testing or clinical trials not addressed in FDA-recognized consensus standards. In other instances, there may be additional requirements (e.g., FDA performance standards in 21 CFR Parts 1010 - 1050 for electronic products) applicable to the device that is the subject of the submission. When a submission contains a submitter's Declaration of Conformity with one or more FDA-recognized consensus standards, FDA reviews the premarket submission to ensure the Declaration of Conformity 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 and FDA-recognized consensus standards with requirements and/or cited reference to other normative requirements do not have precedence over existing FDA laws and regulations. If there is a conflict in requirements, FDA's statutory and regulatory requirements must be met.

List of References

1. OMB Circular No. A-119, Revised Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, February 10, 1998. Available at: http://www.nist.gov/standardsgov/omba119.cfm

2. *Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards* (September 17, 2007). Available at: http://fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm

3. *Frequently Asked Questions on Recognition of Consensus Standards* (September 17, 2007) Available at: http://fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm

4. *CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition* (September 17, 2007) Available at: http://fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077307.htm

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

6. Standards Incorporated by Reference Database, National Institute of Standards and Technology. Available at: http://standards.gov/sibr/query/index.cfm

7. Standards Data Report for 510(k)s. Available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/default.htm